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PRINCIPAL INVESTIGATOR: Seong K. Mun, Ph.D.

CONTRACTING ORGANIZATION: Georgetown University
Washington, DC 20007

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14. ABSTRACT

The Medical Vanguard Diabetes Management Project was designed to deploy an Internet based diabetes management system, MyCareTeam, into a number of existing diverse clinical environments and evaluate how such a stand-alone clinical information system can be integrated into diabetes management program. The diverse environments include the High-Risk Pregnancy Clinic at the National Naval Medical Center and Native American Communities throughout the United States. The GAO Report *Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89)* will be used as the basis for the evaluation of the technology implementations. Enrollment of patients is set to start in two Native Communities, and the IRB process almost complete in two others. The processes required to implement this technology into diverse communities will be studied. This project has two primary specific aims: clinical deployment and deployment evaluation.

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Table of Contents

Introduction:

The Medical Vanguard Diabetes Management Project was designed to deploy an Internet based diabetes management system, MyCareTeam, into a number of existing diverse clinical environments and evaluate how such a stand-alone clinical information system can be integrated into existing diabetes management programs. The diverse environments include the High-Risk Pregnancy Clinic at the National Naval Medical Center (NNMC) and Native American Communities throughout the United States. The GAO Report *Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89)* will be used as the basis for the evaluation of the technology implementations. One Native site has completed their participation in the program, one is on hold, 2 are actively recruiting and the last is maintaining previously enrolled patients but is not actively recruiting more patients. The clinic at NNMC is still actively enrolling patients and monitoring their patients through delivery. The IRB process has been completed at all sites and approval received. This project has two primary specific aims: clinical deployment and deployment evaluation.

Body:

I.   *Statement of Work:*

The approved Statement of Work for this project has two primary aims – *clinical deployment* and *deployment evaluation.* During this third year, much time has been spent on clinical deployment of MyCareTeam at multiple sites and recruitment and enrollment of participants. The administrative processes of setting up subcontracts, working through the Human Subjects Review Processes for each institution, and coordinating with the multiple sites have been challenging but were completed. This report will present the challenges and successes of deploying this technology into diverse clinical environments and then identify the operations that will continue this year and the evaluation procedures to be undertaken.

II.   *Clinical Deployment:*

As we deploy MyCareTeam in multiple Department of Defense (DOD) and Native American healthcare environments, we approach this technology insertion from a global perspective that includes concerns of the enterprise (DOD or Native American facility), existing diabetes management programs, healthcare units, clinical staff, and patients. The goal of the deployment of MyCareTeam is to improve the effectiveness of various existing diabetes management programs for the medical beneficiaries in the DOD as well as Native American Communities as measured by improved health outcomes and clinical care delivery.

The clinical deployment portion of this project focuses on determining the most efficient and effective way to identify and organize the roles and responsibilities of individuals within the healthcare enterprise and the insertion of MyCareTeam within the healthcare delivery system. A comprehensive systems approach to the integration of MyCareTeam into the different clinical environments has been undertaken.

All clinical deployments go through many stages before MyCareTeam can be used effectively. Program setup and recruitment are two critical components of deploying MyCareTeam into an existing clinical environment. The stages of (A) program setup and (B) recruitment and operations that are critical to a successful deployment of MyCareTeam are described here.

(A) Program Setup

1. **secure subcontract for each group**

   At the end of the third year of funding, subcontracts have been created and put in place for all sites. The process for creating new subcontracts has not changed since year 1 and approval was requested from a member of the National Congress of American Indians President's Taskforce on Healthcare Technology to ensure that the monies allocated and distributed to the Native Communities are done so fairly. There are subcontracts in place with the Mandan, Hidatsa & Arikara (MHA) Nation, Poarch Band of Creek Indians (PBCI), and the Native Hawaiian Health organization – Papa Ola Lokahi, the Nez Perce, and with the South Eastern Alaska Regional Health Consortium (SEARHC) on behalf of the Tlingit & Haida Tribes of Alaska. The Wampanoag, Rosebud Sioux, and Mescalero tribes have not progressed despite our efforts to include them.

   The Native Communities submit quarterly reports to us which outline their progress and include an invoice for project related expenses. Upon receipt of year three funding, the subcontracts with PBCI, Papa Ola Lokahi, and Nez Perce and the Cooperative Research and Development Agreement (CRADA) with NNMC are being modified to reflect a three-year agreement. The subcontract with SEAHRC has been terminated and the one with MHA Nation put on hold.

2. **create a local project team including clinical and project management personnel**

   Local project teams have formed for all engaged communities. These teams include clinical, administrative, and project management personnel. Some sites have identified a physician as a member of the team, but most often a nurse or diabetes educator has primary responsibility for interacting with the patients using MyCareTeam. Within each community, an advocate within the health clinic, an administrator or a provider with diabetes knowledge and experience, needs to be identified. This person drives the program from within the clinic. Their job is to coordinate the clinical personnel that will work on the project, identify patients for recruitment, deal with contractual and human subjects' issues, and direct the adjustments that need to be made to the MyCareTeam application. A team of individuals will be involved from the start – but having an advocate makes coordination between the clinical and technical teams run smoother.

   The program manager at the MHA Nation was laid off as we work with MHA Nation to re-evaluate their progress it he program and work together to identify how to get them back on track. Recruitment and enrollment was very slow and therefore we all thought it best to halt execution of the program until we could determine how to improve the numbers. The project team within the Native Hawaiian Health System (NHHS) has changed often over this past year. It has finally settled down and Principal Investigators from each of the two health clinics involved have been identified, and an administrative person from the NHHS is coordinating the two clinics and clinical consultants to work with each site. SEAHRC has decided to halt execution of the project in Alaska because they were not able to recruit ore enroll enough patients. PBCI is continuing to monitor the patients previously enrolled but will not actively recruit or enroll others. Nez Perce continues to monitor the patients they have enrolled and to identify ways to recruit more patients like by lowering their A1C limit for inclusion. NNMC has a project team consisting of physicians, residents, and nurses. The nurses deal

directly with the high risk patient population to recruit and manage their care, but the residents are responsible for communicating with the patients via MyCareTeam.

3. **define the existing health services at each site**

NNMC is a full service medical institution providing primary and specialty care to all members of the armed services and their families. NNMC has the facilities to perform lab tests, surgery, rehabilitation, and other services associated with a full service in– and out-patient medical institution. The Native communities engaged in the project tend to be more single clinics focusing on primary care with some specialty services provided. Most do not have surgery departments, rehabilitation, or therapy (PT, OT, or radiation). They do provide pharmacy services, some provide laboratory services, and most have a nurse practitioner or family medicine doctor that visits the clinic regularly but is not on full time staff at the clinic. Some patients in the Native Communities need to travel many hours to the nearest hospital or specialty clinic (like dialysis) and thus access to care for these populations is limited and difficult.

4. **define the existing diabetes services at each site**

NNMC has two clinics that focus on the treatment of pregnant women with diabetes. They have a gestational diabetes mellitus (GDM) clinic that focuses on women who are pregnant and develop diabetes during their pregnancy but can control their blood sugar levels through diet and exercise. Most of these women do not take medication for their GDM. The other clinic is the Complex Obstetrics (COB) clinic that focuses on pregnant women with pre-existing diabetes or pregnant women who developed GDM but need insulin or oral medications to control their diabetes. Patients from both of these clinics will be enrolled in the study as long as they use a glucose meter to track their blood sugar readings.

Most of the Native Communities have implemented diabetes clinics within their primary medicine clinics. Some of the communities have endocrinologists as consultants that visit their patients periodically or to which they refer their patients, all have glucose meters and supplies available to their patients at no cost, and all of the clinics provide educational classes to their patients on diabetes. One of the clinics provides a monthly foot clinic where patients can get appointments to have their feet examined and cared for. (Foot ulcers leading to amputation is a very serious and common complication of diabetes). One of the sites we are currently working with was using a standalone software application to read their patients' glucose meters when the patients came in for their regularly scheduled visits. All are excited about using our technology.

Table 1.0 below shows the statistics for each clinic enrolled in the project. It identifies baseline information regarding the clinic and existing diabetes programs.

	Number of members	Number of diabetics	Number of clinics	Glucose meter
National Naval Medical Center		15-30 at a time	2 – GDM and COB	AccuChek Advantage
MHA	10800	680	5	AccuChek Advantage
PBCI	2260	300	1	Precision Xtra
Tlingit & Haida	6000	160-180	1	AccuChek Advantage
Nez Perce	5000	406	2	OneTouch Ultra
Hawaiian Natives				
Na Pu'uwai	65	18	4	OneTouch Ultra
Ke Ola Mamo	1485	82	1	OneTouch Ultra

Table 1.0 Site Statistics

5. **define the technology resources available**

The implementation of MyCareTeam requires some home monitoring technology. Patients connect their glucose meter to a vital signs modem device which connects directly to a phone line. The modem reads the data from the glucose meter and transmits the readings to the MyCareTeam database. Initial concerns about the availability of telephone lines, computers, and Internet access within some of the more remote Native communities has not shown to be a problem.

Access to computers and knowledge of the Internet is more difficult. At most sites, excluding NNMC, a small number of their mostly adult patients with type 2 diabetes have access to a computer and an even smaller number have Internet knowledge. Therefore, most of the sites placed public access computers with Internet access in key locations making them accessible to patients.

High speed access to the Internet from the public use machines is available for most sites. Most patients with a computer in their home or a family member's home use dial-up access to the Internet. A toll-free number is in place at the ISIS Center, Georgetown University to receive the glucose readings from the patients modem devices. The modem devices are pre-programmed to send data to this number before they are distributed to patients.

6. **define the clinical protocol to be carried out**

Each site determined for itself the best way to integrate MyCareTeam into their existing diabetes management program. The protocols for each of the Native communities and the NNMC are summarized here. Each site will survey their participants within 2-4 weeks of enrollment and then again 8-10 weeks later. A copy of the survey was included in the 2005 Annual Report.

Mandan, Hidatsa and Arikara Nation (MHA Nation): Patients were recruited from the Parshall and White Shield Health Facilities on the Fort Berthold Reservation. The study nurses at each clinic selected participants who were compliant with their treatment regimen but who still had diabetes that was not well controlled. Participants were also selected on their ability and willingness to access MyCareTeam via the Internet for a period of six months and: had A1C greater than 7 in the last two months (per February 2006 protocol amendment); cur-

rently used a standard glucose meter; were over 18 years of age; had access to a standard telephone line; possess the ability to read and write English and a computer screen. Once enrolled, the participants were followed by the study nurses. Participants were asked to transfer their glucose meter data weekly to the MyCareTeam secured database. Once the data was available on MyCareTeam, patients and providers reviewed the data and communicated via the site. Changes in medication regimen and suggestions for diet and exercise adjustments were made through MyCareTeam. MyCareTeam was to become part of routine care by the health facility staff in managing the recruited diabetic patients during this evaluation project.

MHA Nation hired a study coordinator and an assistant to work on the project. These individuals were tasked with the following: budget and vendor management; provide quarterly reports to the ISIS Center; website and modem orientation for all research staff and participants in the project; travel, as needed, to participants' homes for additional instruction and technical support; documentation of all recruitment efforts and technical support issues for later evaluation; conduct surveys at appropriate intervals; and maintain all regulatory documents as outlined in the study protocol.

Poarch Band of Creek Indians (PBCI): The PBCI clinical protocol is similar to MHA Nation's described above. Patients are recruited by the study nurse come from a population of diabetic patients seen at the PBCI Health Clinic, the only health facility on the reservation. All providers are employees of the health clinic. The nurse reviews the data via MyCareTeam and communicates information back to the patient after consulting with either the staff physician or nurse practitioner in the health clinic. Both of these providers have direct access to patient data on MyCareTeam.

Nez Perce: One full time study coordinator was hired by the Nimiipuu Health Clinic to conduct this study. Another part time coordinator worked for several months assisting the study coordinator at the beginning of the recruitment and enrollment period. Once trained on the use of the technology, the study coordinator trained the provider/nurse teams at Nimiipuu Health who work with diabetic patients, the pharmacist, the nutritionist, and the diabetes educator who all monitor and manage the participants' diabetes. The inclusion criteria identified above for the MHA Nation study is used at the Nimiipuu Health Clinic.

Tlingit & Haida: For this segment of the study, patients were recruited from the South Eastern Alaska Regional health Consortium (SEARHC) Medical Center in Juneau, Alaska. The study nurse selected patients with poorly controlled diabetes but who are able and willing to access MyCareTeam via the Internet for a period of six months. The inclusion criteria were the same as the MHA Nation. During the course of the study, patients were followed by the research nurse at SEARHC using the MyCareTeam system .

Papa Ola Lokahi: Papa Ola Lokahi coordinates the project being executed at two Native Hawaiian Health clinics in Hawaii, Na Pu`uwai on the island of Moloka`i and Ke Ola Mamo Native Hawaiian Health Care Systems (NHHCS), on O`ahu. Both of these clinics have a study nurse who recruits participants, trains them in the use of the MyCareTeam system, and also monitors the blood sugar levels and receives and senda messages to participants.

To ensure participant confidentiality, per a requirement of the Native Hawaiian Health Care Systems IRB, a specially designed registration process is used to identify participants within the MyCareTeam system. To create a de-identified username and password, the subject is assigned a study number (i.e. 082) and an alias as the "first name" (i.e. Minnie). A subject "log in" is then automatically created by combining the study number and the first three letters from the first name field (i.e. 082-Minn). Only the local Research Team has access to the "master list" of patients to assure that care is provided to the correct client. The same inclusion criteria as outlined for MHA Nation are used at these sites.

All Native American Sites: All participants at the Native American sites complete two patient satisfaction telephone surveys: the first 2-4 weeks after enrollment in the study and the second 2-4 months later. The surveys provide incite into each participants' satisfaction with the MyCareTeam technology, communicating with their care providers using the technology, and the usefulness of the online educational materials. Survey results are analyzed and if and where deficiencies are found in the MyCareTeam system, modifications are implemented. Survey results also guide the modification of the technology to address both cultural and clinical diversity. Throughout the study, we will continue to reassess the system and make changes as needed.

National Naval Medical Center (NNMC): Patients are recruited from the Complicated Obstetrics (COB) and the Gestational Diabetes Mellitus (GDM) Clinics at NNMC in Bethesda Maryland. Participants come from a population of pregnant women who have either preexisting diabetes or who have been diagnosed with gestational diabetes. Patients are eligible for the study if they meet the following criteria: pregnancy is complicated by either type 1 or 2 diabetes or patient is diagnosed with gestational diabetes; the participant is less than 32 weeks pregnant; they regularly test blood glucose levels using a standard glucose meter; they can read and write English; and they are over 18 years of age.

Patients transfer their blood glucose readings twice a week to the MyCareTeam secured database using the AccuLink Modem or by connecting their glucose meter to a personal computer. The GDM and COB residents and nurses examine the information online. The residents can change orders for the patient's regimen and message the change back to the patient via MyCareTeam. Patients are instructed to review their own data on MyCareTeam and to look for messages from and send messages to their providers using the system. Patients are given a survey two-four weeks after enrollment and again at approximately 35-38 weeks of pregnancy. The survey helps us to understand their reaction to the technology implemented through MyCareTeam, how they felt about communicating with their care provider over the Internet, and their feelings towards the educational materials.

7. **determine where the database and web servers will be hosted and managed**
Due to monetary constraints and technical expertise, all sites have opted to have the ISIS Center at Georgetown University host the web and database servers. Toll-free telephone numbers have been setup to facilitate the transfer of data directly from the glucose meters via the modem devices to the MyCareTeam database. The computer facility at the ISIS Center is a locked room in a secured facility. It is protected by electronic firewalls and VPNs as need

to ensure the safety and integrity of the clinical data. 128-bit secure socket layer encryption insures that no unencrypted confidential information is sent over the Internet.

8. **secure human subjects approval from all necessary institutions**
Human subjects' protections are a large piece of getting this program underway. Before recruitment of study participants can begin, authorization must be received from three separate human subjects approval agencies or institutional review boards (IRB). The first agency is Georgetown University. We first received expedited review approval from the Georgetown University IRB on August 21, 2003. We have since received three additional continuing approvals with the next due on June 13, 2007.

The second human subjects' approval comes from the regional IRB for each of the American Indian, Alaskan Native and Native Hawaiian communities and NNMC and is referred to as the primary IRB approval. Each study site submitted a protocol and consent form adapted to their individual needs. The Native American and Alaskan Native communities received approval from the local Indian Health Service (IHS) IRB committees. The PBCI received authorization to carry to the study from IHS Headquarters in Bethesda, Maryland since the regional IHS IRB is not operational at this time. The local area IHS IRB committees are located in Anchorage, Alaska; Aberdeen, North Dakota; and Portland, Oregon. Primary approval for the Native Hawaiian study will come from Papa Ola Lokahi, a Native Hawaiian Healthcare System providing human subjects approval on projects related to Native Hawaiian Healthcare. NNMC has its own IRB committee.

The third and final authorization came from the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command. This is referred to as secondary approval.

The chart below shows the dates that primary and secondary IRB approval was received for each site.

Institution	Primary Approval	HSRRB Approval	Continuing Review Approval Due
NNMC	1-25-05	1-4-05	4-1-07
MHA	5-5-05	6-15-05	11-20-06
PBCI	9-1-04	3-17-05	8-31-07
Tlingit & Haida	8-31-05	2-27-06	8-31-06
Nez Perce	6-6-05	2-14-06	6-5-07
Hawaiian Natives Na Puuwai Ke Ola Mamo	12-9-05	3-15-06	12-8-06

Table 2.0 Human Subjects' Approval

9. **review the MyCareTeam site for modifications, setting defaults, creating accounts**
During the first year of the project, the IHS diabetes curriculum was integrated into the web site to provide diabetes education materials to the Native communities. All of the Native

American Communities, including the Hawaiian Natives, agreed to use this educational information for their patients. During this past year, the Hawaiian clinics identified areas of the application that should be modified to make the software more culturally appropriate. The look and feel of the lobby was updated to include a more Hawaiian looking receptionist, and to use Hawaiian words. The outside of the building was also updated to include Hawaiian vegetation. The personnel at the Hawaiian clinics also requested that we allow them to track cholesterol medications for their patients like we do for hypertension medications. This is currently being implemented.

Some other changes that have occurred were at the request of the NNMC. We created a mechanism that their patients could directly connect their glucose meters to a computer and bypass the use of the modem device. More and more of the NNMC patients did not have land line telephones at home. NNMC personnel also requested that a prescribing page and tracking page for insulin pump users be incorporated. This is underdevelopment.

Configuration of the sites for the Nez Perce, Tlingit & Haida Tribes, and the Hawaiian Native communities was completed this past year. All clinicians at each site were trained to use MyCareTeam during this year.

10. procure technology including blood glucose meters, modem technologies, cables, computers, install communications lines, setup telephone numbers
The technology necessary to transfer blood glucose readings from the glucose meters to the MyCareTeam database was procured for all sites. NNMC continues to use the AccuChek Advantage glucose meters and thus the AccuLink modem to transfer the data from the meter to the database. SEAHRC also used the AccuChek meters and AccuLink modems. During this past year, MHA Nation switched from using the AccuChek Advantage meter to the Precision Xtra meter. This resulted in a change in the modem device used and thus precipitated the temporary hold being placed on the operations of the project at MHA Nation. MHA Nation sent their AccuLink modems to us at Georgetown and their cables to SEAHRC in Alaska. Unfortunately the box containing the cables got lost and was never recovered. The modems arrived safely and can be used by other sites if any are added to the program that use the AccuChek glucose meters.

PBCI uses the Precision Xtra meter and thus uses the AeroTel TeleCliniQ to transfer the blood glucose readings from the meter to the MyCareTeam database. AeroTel increased the price of their modem this past year to $170 each from $150, although this is still a discount from their retail price of $250. The PBCI buys the cables connecting the glucose meter to the modem directly from the glucose meter manufacturer. The manufacturer has provided some cables free to the site.

The Nez Perce site and the Hawaiian Health clinics both use the Lifescan OneTouch glucose meters and the Aerotel TeleCliniQ modems. The LifeScan representative has generously provided meter cables free of charge to the sites.

Two toll-free numbers continue to operate at the ISIS Center to accept the data transmitted from the TeleCliniQ and AccuLink modem devices.

11. train clinical personnel

Personnel from SEAHRC, Nez Perce and the two Hawaiian Health Clinics were trained at the ISIS Center this past year. No retraining was required for the MHA Nation, PBCI, or NNMC personnel. We still provide a certified diabetes educator to the NNMC site to aid in training the new residents rotating through the clinic and handling administrative issues such as enrolling patients, training the users on the system, entering lab results and entering medications.

(B) Recruitment and Operations

1. Define inclusion and exclusion criteria for patient participation

Native American Sites:

Inclusion	Exclusion
Have type 1 or type 2 diabetes mellitus that has been diagnosed for at least 6 months.	Less than 18 years of age
Have an A1c value ≥ 7 in the last two months	Unable to read and write English
Currently using a standard glucose meter	Unable to read a computer screen
Have access to a Plain Old Telephone System (POTS) line	

National Naval Medical Center:

Inclusion	Exclusion
Pregnancy is complicated by either type 1 or 2 diabetes or patient is diagnosed with gestational diabetes	Less than 18 years of age
Patient regularly tests blood glucose levels using a standard glucose meter	Patient has a significant medical co-morbidity that would inhibit their ability to use MCT
Have access to a Plain Old Telephone System (POTS) line	Patient has a history of serious psychiatric disorder
Patient can read and write English	Patient's physician has objections to her participating in the study
Have access to a computer and the Internet	

2. identify recruitment procedures

Each site has determined the best way to recruit their patients. Whether to use public announcements, brochures, or flyers for recruitment is decided by each site individually.

Site	Recruitment Procedure
National Naval Medical Center Bethesda, Maryland	Study nurse meets with obstetrical clinic staff weekly to identify those patients who meet the inclusion criteria. The study nurse then schedules a time to meet with these patients, reviews all study procedures and invites the patient to participate. If the patient consents

		to enroll in the study, enrollment procedures are followed according to NNMC IRB protocol and patient training is completed. Patients are then given the modem to take home along with instructions on how to use it and how frequently to send their data into the system.
Poarch Band of Creek Indians Atmore, Alabama MHA Nation New Town, North Dakota Nez Perce Tribe Lapwai, Idaho Tlingit & Haida Tribes Juneau, Alaska		Individuals are recruited from a population of patients receiving diabetes care from the tribal health clinics. Project investigators select participants who are compliant with their treatment regimen but whose diabetes is not well controlled. During the period of study, a diabetes nurse or member of the research team speaks to patients who meet the inclusion criteria. All project team members involved in the consenting process have completed the NCI Human Subjects Training Program. After informing the patient that they are eligible to participate, the team member gives the patient a brief description of the project. If the patient indicates an interest in participating, the consent form is reviewed with them and all questions the patient may have are answered. If the patient consents to enroll in the study, enrollment procedures are followed according to local IHS area IRB protocol and patient training is completed. The original signed copy of the consent form is placed in the patient's medical record and the patient receives a copy for their records. Patients are then given the modem to take home along with instructions on how to use it and how frequently to send their data into the system.

3. **identify incentives, if any, that will be used**
The only site truly using incentives to encourage participation is the Nez Perce. The study coordinator at Nimiipuu Health created a step-program to administer incentives for study participants. People who attended an informational meeting about the study were given "Diabetes for Life" magnets. Once an individual agrees to participate and is enrolled, they are eligible for a step program for receiving incentives. The first time one sends in their data they are sent a pedometer. If they then downloaded two times in the next two months and logged in to the site once each month they receive a Nike t-shirt embossed with the diabetes program logo. Lastly, if a participant checked their blood sugars at least 6 times per week for 4 weeks

they received a pair of running shoes from Nike.net. And finally after completing the study, participants will receive $50. This information is being shared with the other sites and they are being encouraged to develop their own set of incentives.

4. **gain consent**
   Consent forms have been created and primary and secondary approvals received for all sites.

5. **Summary of Program Setup**
   A summary of the progress of the program setup is provided below in Table 3.0.

Principal Investigator: Seong K. Mun, PhD

	MHA	PBCI	Papa	Tlingit and Haida	Gay Head	Nez Perce	Rosebud	Mescalero	NNMC
(A) Program Setup									
Subcontract/CRADA	X	X	X	X		X			X
Project Team	X	X	X	X		X			X
Health Services	X	X	X	X	X	X			X
Diabetes Services	X	X	X	X	X	X			X
Technology Resources	X	X	X						X
Clinical Protocol	X	X	X	X	X	X			X
Host Servers	X	X	X	X	X	X			X
Human Subjects	X	X	X	X		X			X
Modify My-CareTeam	X	X	X	X		X			X
Procure Technology	X	X	X	X		X			X
Training	X	X	X	X		X			X
(B) Recruitment									
Criteria	X	X	X	X		X			X
Procedures	X	X	X	X		X			X
Incentives		None	None	None		X			None
Enrolled	X (10)	X (25)	X (16)	X (13)		X (29)			X (35)

Table 3.0 Program Setup

X – completed (number enrolled)

W81XWH-04-2-0002

III.   *Deployment evaluation*

(A) Introduction
This section focuses on evaluating whether the insertion of MyCareTeam into routine delivery of healthcare services and specifically chronic disease management was effective.

The earlier indications of the effectiveness of MyCareTeam as a stand-alone specialty disease management e-health system are encouraging. However, insertion of MyCareTeam into multiple diverse clinical environments presents new technical, clinical, management, and cultural challenges.

During this past year, Inyoung Choi, PhD joined our team and worked closely with Jim Grigsby, PhD to redesign and develop the evaluation process. The Chain of Events analysis outlined in the GAO report will be used where appropriate. Dr. Choi has developed an evaluation framework that addresses three-phases of evaluation: Planning, Implementation, and Monitoring. Each of these phases is then evaluated based on Operational, Technical, Security and Outcomes foci.

This section describes our evaluation effort of the implementation of MyCareTeam and proposes how a web-based diabetes management application can be integrated into diabetes management programs. Towards this end, we took the following steps:

(i)   Developed a performance evaluation model that aligns with the objectives of the project
(ii)   Identified how to implement MyCareTeam into diverse communities and evaluate its effectiveness.

Towards this end, we identified three phases of the evaluation process: planning, implementation, and monitoring. Each of these phases must focus on different aspects of operational, technical and security features.

Planning phase
The goal of the planning phase is to define the operational, technical, and security features necessary to implement MyCareTeam that meets patients' and clinicians' expectations and results in patients' satisfaction of their diabetes management. The operational tasks that are part of the planning phase are to develop an appropriate project team, to define and understand the existing diabetes management process, and to successfully navigate the IRB process. The technical tasks are to identify and verify that the technical infrastructure exists at each site to carry out the project and then to define the modifications of the MyCareTeam application requested by each site.

Implementation phase
The goal of the implementation phase is to define the operational and technical features that enable MyCareTeam to work well in diverse sites. The operational tasks include training for patients and providers, developing recruitment criteria that permit the identification of a sufficient participant population, and recruiting of patients. The technical tasks include integrating the MyCareTeam application with the glucose meters and modems used at each site and insuring the clinicians have access to all their patients' data via the Internet. This includes defining and im-

plementing site parameters and site specific changes to the web site and insuring secure access for all.

Monitoring phase

The goal of the monitoring phase is to monitor the compliance of operational, technical and security features once MyCareTeam is implemented in the diverse healthcare settings. In addition, the quantitative evaluation of clinical and other outcomes data, like patient's satisfaction, will be conducted to explore the how MyCareTeam can be inserted into clinical care settings outside of research studies.

(B) Project evaluation Model

GAO's IT Performance Measurement Guide (1998) states that performance evaluation standards should align with the mission and objectives of the project. Performance measurements define how information technology can contribute to desired improvement in outcomes.

The objective of the Medical Vanguard Diabetes Management Program is to improve the diabetes management process in diverse clinical settings by introducing a web-based diabetes management application. To accomplish this goal, intermediate efforts along with final outcome are measured and evaluated.

Performance evaluation will include measurement of the planning, implementation and monitoring phases in terms of operational, technical, security and outcome perspectives as diagramed in Figure 1.0. Therefore, our evaluation of this project will determine how well the broad objectives and intermediate goals we set for each phase of the project, as outlined above, were met.
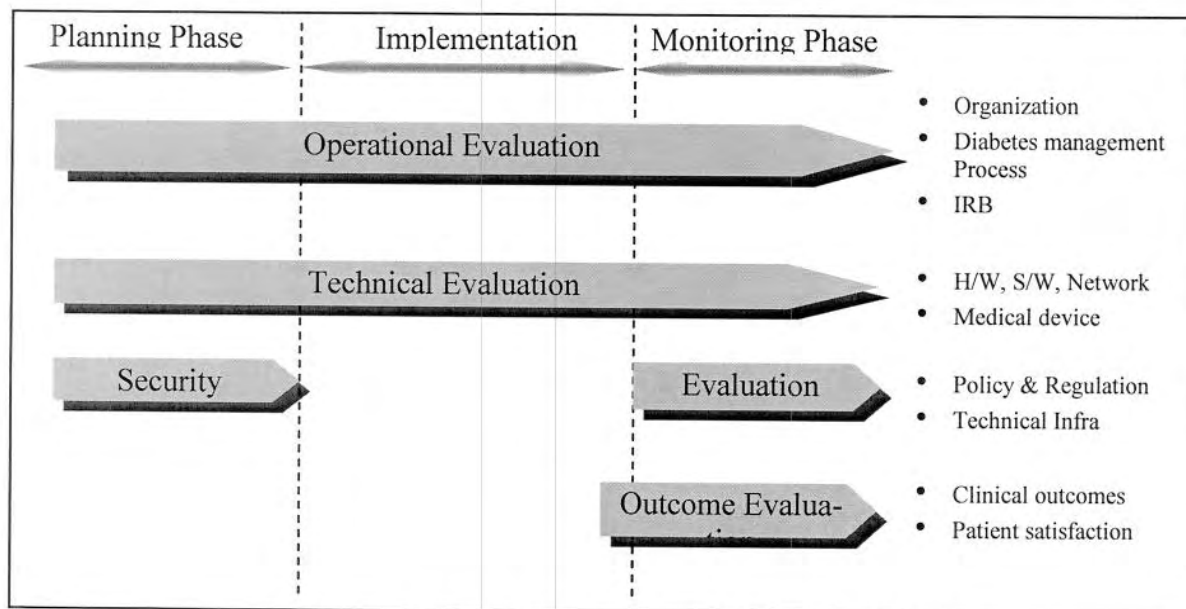

Figure 1.0 Project roadmap and Evaluation Model

PLANNING PHASE

The evaluation of the planning phase assesses the operational, technical and security features related to the implementation of the project. The categories and key evaluation measures are listed in Table 4.0 for the operational, technical and security features required during the planning phase.

Category		Key Evaluation
Operational feature	Create project team	• Develop team • Assign responsibility
	Identify diabetes management process	• Identify provider roles • Identify clinic visit • Monitor A1C levels
	Attain IRB approval	• Define protocol • Average time spent
Technical feature	Define Modification requirements	• Communication with local clinics • Apply user's requirements
	Setup technical infrastructure setup	• Setup communication line • Prepare H/W • Install S/W
Security feature	Evaluate current infrastructure	• H/W, S/W infrastructure compatibility • Network configuration • System configuration
	Define security requirements	• Develop H/W, S/W, network requirements
	Define threats and security roles	• Role creation • Create accounts • Access control and authentication
	Develop security policies	• Documentation of security policy

Table 4.0 Key Evaluation Components for the Planning Phase

Operational evaluation – Project team

An interdisciplinary team including clinical, administrative, technical and project management personnel from ISIS and the local clinics were established and their roles defined (Figure 2.0). The details for each position are as follows:
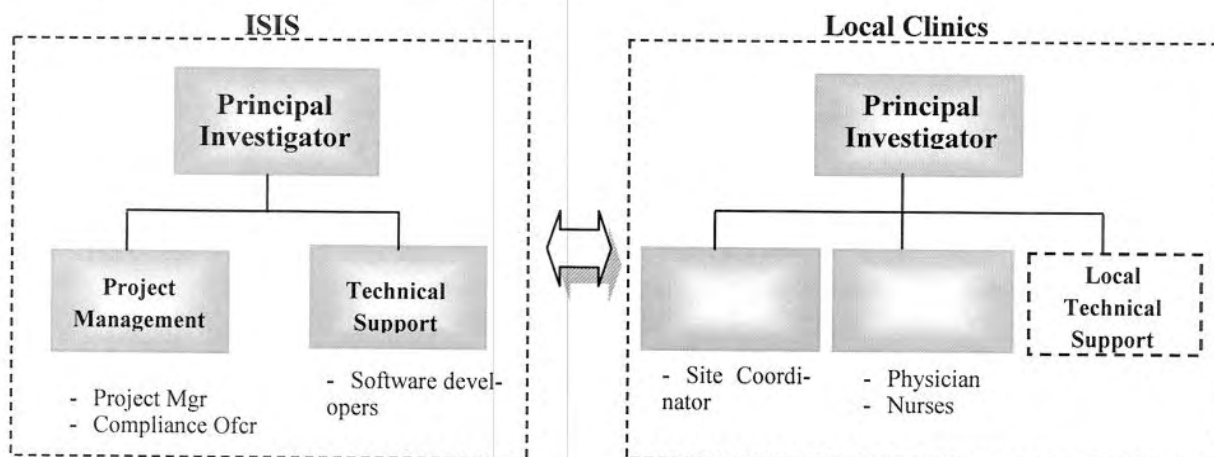

Figure 2.0 Project Teams and Roles

ISIS

ISIS management of the Medical Vanguard Diabetes Management program relies on a multitude of individuals committed to project management and technical development and support: The Principal Investigator, The Project Management Team, and the Technical Team.

The Principal Investigator supervises the entire project process

The Project Management Team includes a Project Manager that handles the day-to-day operations of the program; a compliance office that handles the human subjects' approval process; an administrator to mange financial components, and an evaluator to analyze the progress of the project. Some of the responsibilities of the Project Management Team include
- Monitoring usage per site
- Managing contracts and invoices
- Training users
- Administering user surveys
- Evaluating the project

The Technical Team includes software developers, network administrators and technical support personnel. Some of their responsibilities include:
- Reviewing the MyCareTeam software with the sites and modifying the software as identified
- Configuring each new site
- Setting up the modem servers
- Maintaining the web and database servers
- Providing telephone support
- Developing new features as needed
- Incorporating educational materials and new News articles as requested
- Monitoring the site & database daily

Local clinics

Local management of the Medical Vanguard Diabetes Management program relies on a multitude of individuals committed to project management, clinical operations, and support: The Principal Investigator, The Project Management Team, and the Clinical Team. Some sites also have onsite technical support while others rely on their project team for first line support and then the ISIS Center for further support.

The Local Principal Investigator
- Supervises the implementation process of MyCareTeam
- Handles contract issues
- Works with ISIS to navigate the local human subjects committee

The Project Management Team

Some sites have identified a project coordinator that has clinical knowledge and experience regarding the management of diabetes, while other sites have focuses on someone that can handle the day-to-day operations of the site and leave the clinical management to the Clinical Team.

The Project coordinator drives the program from within the clinic and may rely on a team to cover the other responsibilities including:

- Recruiting and enrolling patients
- Creating the patient record within MyCareTeam
- Training patients and other providers
- Encouraging and tracking patients' use of the technology
- Providing operational support and 1st line of technical support
- Procuring modem devices and cables
- Preparing invoices

The Clinical Team

The Clinical Team may contain nurses, nurse practitioners, physicians, physicians' assistants, dieticians, certified diabetes educators and others depending on the availability at a given clinic. Their responsibilities include interacting with the patients and their data through the My-CareTeam application. The team's responsibilities include:

- Reviewing blood glucose readings on the site
- Entering laboratory results into the site
- Entering medication changes
- Messaging with patients and other providers

Issues and recommendations

While evaluating the results of the planning phase, we identified some things that worked and some that could have been handled better. They will be identified here.

Issue: Developing the appropriate Teams

Each site needs to have a strong project coordinator, clinical personnel, and good support from their tribal or larger facility. While it is critical to identify potential participants, it is as critical that the providers use the site so that they communicate with the participants using the site. This will encourage the participants to continue using the system.

Recommendation: Find a strong clinical advocate

Getting a strong clinical advocate to work with your Project coordinator or Project management team will make for a smoother transition. Nurses and physicians are very busy, so if they see this as an added burden and not something they have bought into, it will be difficult to be successful. The sites that had both strong project coordination and strong clinical advocates were the most successful identifying, recruiting, enrolling and monitoring patients.

Issue: Local technical support

It is important to have someone on the project management team who is comfortable with technology or to have some local technical support. Questions from patients, problems with modems or phone lines can interrupt forward progress with the project.

Recommendation: If the patient population is not computer savvy and the project management and clinical teams are not either, having access to local technical support would be helpful. Often, many issues that seem to take a while to figure out could be handled more quickly if there is good local technical support working with the ISIS technical support team.

Each clinic had a process established to manage their diabetic patients. The PBCI health clinic has "Diabetes Day" each Tuesday where they schedule approximately 250 patients with diabetes for their clinic visits, lab tests, foot clinic, nutrition counseling and more. Similarly, MHA Nation has a "Diabetes Day" once a month when tribal members can come in and have their feet checked, talk with a dietitian, or go over their glucose readings. Most of the patients with diabetes within the Nez Perce tribe are seen at the main clinic on the reservation. These individuals are treated by a team of clinicians to help manage their diabetes. There does not seem to be any set days for these patients to be seen. The two Hawaiian clinics have similar approaches to diabetes management. They both teach their patients how to manage their diabetes. The Na Pu'uwai clinic on Molokai also offers case management, education and outreach programs for their diabetic patients. The diabetes program at SEARHC provides an RN/case manager, a clinical dietitian, physical therapy, foot care, and wound care. At NNMC, diabetes management of the pregnant women is handled by either the Complicated OB clinic or the Gestational Diabetes Clinic. Nurses, attending physicians, residents, and a dietitian work with these women to care for their pregnancy and their diabetes. The clinical staff within these clinics offers educational classes and training on managing diabetes and injecting insulin as needed. The dietitian works with each woman individually to teach them about the importance of diet and exercise on diabetes and pregnancy.

Each clinic provides glucose meters and strip to all their patients for free. The Indian Health Service provides the meters and strips to each American Indian health clinic. The Native Hawaiian Healthcare system provides them for the Native Hawaiian population and the US Navy provides them for the NNMC patients.

It was very important to understand the existing diabetes management programs at the sites before inserting the MyCareTeam technology into the health clinic. The sites with well defined programs had an easier time implementing the technology into their program. Those sites with not as well defined process in place had more difficulty identifying how the technology could work within their existing structure.

Operational Evaluation - IRB approval
Receiving human subjects' protection approval was critical before any patients could be enrolled into this program. Authorization from three separate human subjects' approval agencies or institutional review boards (IRB) was required: Georgetown University; Primary approval from local IRB; Secondary approval from the funding agency.

Georgetown University human subjects' expedited review approval was received first on August 21, 2003. The continuing approvals have been received with the next due on June 14, 2007.

The second human subjects' approval came from the regional IRB for each of the American Indian, Alaskan Native, and Native Hawaiian communities, and for National Naval Medical Center (NNNMC). These are referred to as the primary IRB approvals. Each study site submitted a protocol and consent form adapted to their individual needs. The Native American and Alaskan Native communities received approval from various Indian Health Service (IHS) IRB commit-

tees. For those IHS sites where there was no active local IRB, authorization came through IHS Headquarters in Bethesda, Maryland. The various IHS area IRB committees are located in: Anchorage, Alaska; Aberdeen, South Dakota; and Portland, Oregon; Primary approval for the Native Hawaiian study came from the Native Hawaiian Healthcare Systems IRB. NNMC has its own IRB committee.

The third and final authorization came from the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command. This is referred to as secondary approval. The chart included above in the program setup section number 8 lists the dates that each site received primary and secondary IRB approval.

Issues and recommendations

Issue: Dealing with multiple Institutional Review Boards
At the start of the project, each study site submitted a protocol to their local IRB for approval. The local IRB would review the protocol then send it back to the site, sometimes as much as **4-6** months later, requesting that portions of the document be revised. Study personnel made the revisions and the document was resubmitted for approval. This process was often repeated several times before final authorization was received. Once approved by the local IRB, the protocol was sent to HSRRB at USAMRMC to undergo an even more rigorous review and revision. Any revisions imposed by HSRRB had to again be approved by the local IRB.

Recommendation: Submit the protocol to HSRRB first. Since their review process is more rigorous, errors in the protocol can be corrected before it is ever sent to the local IRB. In turn, the local IRB starts with a superior product, which has the potential to decrease the time it takes for the Board to give their approval. If the local IRB does make a change, it will most likely be a minor one that can be quickly reviewed by HSRRB and approved.

Issue: Dissemination of project results
One local IRB had concerns about control and dissemination of project results. These concerns were based on their experiences in other multi-center projects involving tribal communities.

Recommendation: The local IRB proposed that the Georgetown Contracts Office issues a Data Sharing Agreement. The agreement is between the ISIS Center and the health clinic conducting the study. The agreement covers the follow topics: publishing, use of data, privacy and protection of data and rights of the Federal Government.

Technical evaluation – Software Modifications
One important objective of the Medical Vanguard Diabetes Management Project is to determine the modifications to be made to the user interface of the MyCareTeam software to make it more culturally acceptable to the different Native Communities. To this end, when the software was demonstrated to each site, the project team members (management and clinical) were asked to identify areas of the site that should be changed to make the software more appealing to Native American users. A summary of the changes requested are given in Table 5.0.

All of the Native Communities requested a change to the outside building – the entrance to the MyCareTeam Virtual Clinic. The original image was of a glass and brick high rise and the new clinic image is of a single story rural clinic. The name on the clinic changes for each site, some vegetation was added for the Hawaii site, and the snow which covers the land and falls during the winter was turned off for the Hawaii and Alabama site.

Next, the images in the lobby area of the site were also changed to be more appealing to the Native American users. The colors used in the lobby were changed to be more earth tones; the receptionist was redrawn to make her more culturally familiar. Appendix A contains screen shots of the pages within the MyCareTeam application that have been significantly changed based on the requests of the Native Communities. Another change made to the lobby area was to include some Hawaiian words for the Hawaiian clinics.

Many changes were implemented for NNMC since treating pregnant women with diabetes is different than treating non-pregnant type 1 or type 2 diabetic patients. The blood sugar log book was modified to accommodate the NNMC patients. It is very important to the diabetes management of pregnant women to know when a blood sugar reading was taken in reference to when the woman ate her meal. Therefore, each participant from NNMC must categorize each and every blood sugar reading that is uploaded to the site and mark whether the reading was taken in early am, fasting, post-breakfast, pre-lunch, post-lunch, pre-dinner, post-dinner, or bedtime. The women are also asked to enter whether they modified their insulin or oral medication so that the information is available to the provider. The new blood sugar log book now contains different time slots that correspond to the meal-times listed above and also has their medications displayed in the log book.

Another change that was made for NNMC patients was to allow them to connect their glucose meter directly to their computer instead of using the modem device. It turns out that many of the women who receive their care from NNMC do not have landline telephones at home but only cell phones. These women tend to have high-speed Internet connections so they can access the Internet easily, just not a standard POTS line.

Change Requested	Sites Requesting Changes
Outside of Building	All Native Communities
Lobby Colors & Receptionist	All Native Communities
Use of Native language	Hawaii
Categorization of readings	NNMC
Redesign of blood sugar log book	NNMC
Direct Connection of glucose meter	NNMC

Table 5.0 List of Changes by Site

Issues: Understand the Culture of the people using the site
It is very important hat the look and feel of the web site be desirable to the population that is going to use it. The functionality needs to be appropriate, but if it is not appealing it won't be used.

Recommendation: Work closely to understand the population that will be using the software and spend time with them playing with the site to get their true feedback. It may take a number of

iterations to get the changes right and it may take them using the site clinically before they truly understand their needs.

Technical Evaluation - Infrastructure setup
In order for the MyCareTeam application to be successful, the people using it must be able to transmit their glucose readings from their meters electronically and easily to a secured database. People will need to have some technology convenient to them to make the transfer. Two technologies were identified to make this process easy. First, telephone modem devices were identified that allowed people to connect their glucose meter directly to the device and push a single button to transfer the data out of the meter to the database. The setup on these devices is also quite simple. However, some people no longer have analogue telephone lines at home and then the modem device will not work. For those people, we callow them to connect their glucose meter directly to a serial or USB port on their computer and use and Active-X program to transfer the readings. For this solution, people must have direct access to a PC and the Internet.

At the ISIS Center, modem servers were installed to receive the glucose readings coming from the AccuLink or TeleCliniQ devices. These servers are software provided by the manufacturer of the modem device. Each server can handle only a single telephone line and thus each server needed to run on a separate computer. Currently, we have two modem servers running connected to two separate toll-free phone lines.

Issues and recommendations
Issues: Availability of home telephone lines
While the modem devices are a real simple way to transfer the glucose readings from the meters to the secured database, having a single solution may not be enough. All the Native participants have home telephones, but many of the NNMC participants did not.

Recommendation: The direct connect solution for patients to transfer their readings was required to improve recruitment at the NNMC. If we did not have a solution for people without telephones, our recruitment would have been much slower at NNMC.

Issue: Access to the Internet and Internet knowledge
Most of the Native Communities felt that only a small percentage of their adult patients with type 2 diabetes would have access to a computer and an even smaller number would have experience with the Internet.

Recommendation: Just because people may not have experience with the Internet does not mean they don't want to learn. It is critical to make technology conveniently available to the people in the study so that they can learn to use and become familiar with it. It may also be necessary to have support available at the public sites where people may access the MyCareTeam site.

Security evaluation - Current infrastructure evaluation
MyCareTeam is designed to comply with Health Insurance Portability and Accountability Act (HIPAA) requirements, and implemented security measures assure data integrity and confidentiality. Built-in authentication mechanism and access controls for data access, viewing, and updating. All system components (database and web servers) reside behind a firewall.

The ISIS Intranet is composed of multiple interfaces with rules and policies governing the flow of traffic to different subnets and hosts on those subnets. The web server is located on a demilitarized (DMZ) which is behind the firewall to ward off potential attacks. Only web traffic is allowed to access the server from the Internet. The database is hosted on another server that is connected to a highly secured subnet of the ISIS Intranet. Communication to the database server is encrypted and only the ports required by SQL on the web server are permitted to communicate with the database server. These measures minimize the risk of the web or database servers being hacked or attacked by outsiders; they also prevent insiders from gaining unauthorized access and or altering the data.

A Cisco Pix Firewall 515 E with 6 interfaces is used to protect the ISIS Intranet. All six interfaces of the Cisco PIX 515E firewall are assigned (Figure 3.0) as follows:

"outside"   The outside interface - all traffic to protected segments passes through this interface

"inside"   The Patient Information segment - sensitive Patient information is housed here because there is limited access to this segment

"vpn"   Virtual Private Network Segment – a Cisco 3640 router is used on this segment to permit authorized ISIS users remote access to sensitive parts of the network.

"isis"   ISIS Segment – is where the computers and peripherals used by Members for daily tasks – email, printing, Internet access, etc – are housed

"dmz"   Demilitarized Zone - Contains a number of servers that are publicly accessible but also maintain a modicum of protection from outside attacks

"Prototype"   Test Segment – containing a number of Cisco routers and switches, database servers, and a DNS for application prototyping, development, and testing.

Each interface serves one or more subnets with hosts that require varying degrees of security. The firewall protects all systems within the ISIS Center from unauthorized access and enforces security policies to comply with current standards and regulations including HIPAA.
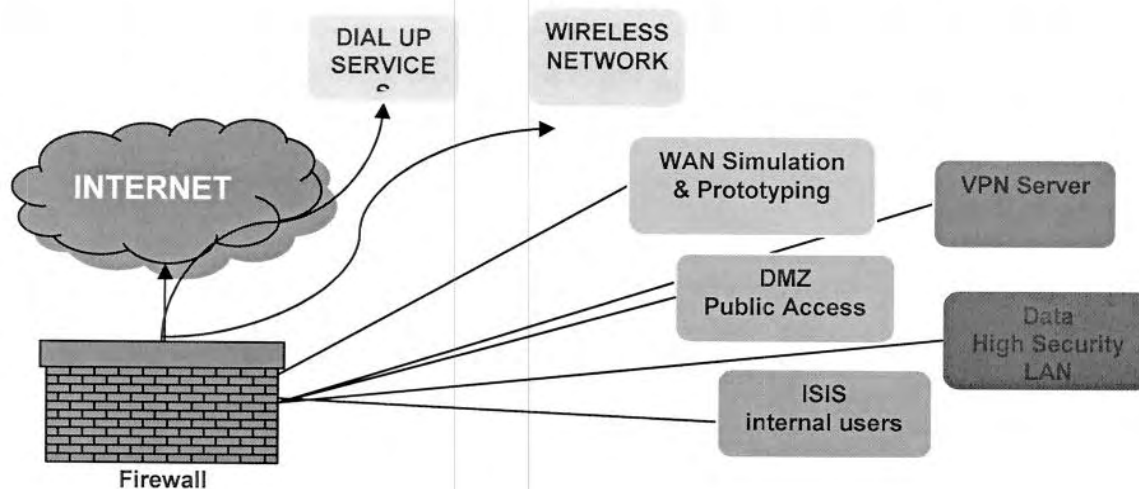

Figure 3.0 Diagram of ISIS Firewall protections

Network and systems scans are conducted to evaluate current information security and data integrity, both in-transit and dormant. As a result, updates and system changes are made to address current security threats. Scans evaluate different levels of security threats such as penetration testing, patching and operating system updates, user accounts, and software updates. The technical team uses scan results to mitigate the risks.

The MyCareTeam application is compliant with the ISIS Center's Information Assurance Policy, which was developed to protect all data from threats that could compromise the privacy, confidentiality, integrity, and availability of information assets. The ISIS Center Information Assurance Policy is included in Appendix B.

IMPLEMENTATION PHASE

The evaluation of the implementation phase assesses the operational and technical features of the MyCareTeam implementation at the multiple sites. The operational and technical features related to the implementation phase are included in Table 6.0

	Category	Key Evaluation
Operational features	Training & Education	• Development of materials • Training
	Patient recruitment	• Develop project protocol • Recruit patients • Enroll patients
Technical features	Setup and implementation	• Configure H/W • Program modems • Install software

Table 6.0 Implementation Phase

Operational Evaluation – Training & Education
MyCareTeam software had basic diabetes educational materials incorporated as part of the site. The Native American Communities opted to use the Indian Health Service Diabetes Curriculum as the material they wanted presented to their participants. During the first two years of the project, the IHS curriculum was converted from a paper based curriculum to one that was appropriate for patients and available over the Internet through the MyCareTeam site.

Similarly, the NNMC clinical team provided new educational materials that they had created as paper-based for inclusion on the Web site accessible to their participants.

Monthly, news articles written by Nicole Johnson, Miss America 1999, are placed on the MyCareTeam site and made available to all users of the site. Nicole writes articles related to the seasons, new advances in diabetes research, and other topics of general interest to individuals with diabetes.

Training of the project management and clinical teams is critical. Training them closer to when they begin enrolling patients is very important. If they are trained too early, they will not remember how to use the site and will require retraining once they begin.

A full-day training program was set up at the ISIS Center and 1-2 members of the project and/or clinical teams were encouraged to attend. The training outline was included in last year's annual report. At the training session, the consenting process, the modem devices, the administrative functions of MyCareTeam, and the monitor and message functions are reviewed.

The trainees are then expected to return to their respective sites and take a train the trainer approach and train others on their project and clinical teams that will interact with the software.

Issues and recommendations

Issue: Preparation of appropriate materials

It is critical that the educational materials presented to the users of the site be appropriate to their situation. The materials presented to pregnant women in an urban area will be very different than that presented to Hawaiian men with diabetes.

Recommendation: Culturally, there are many ways that people deal with and think about chronic diseases and the management of those diseases. Insuring that the educational materials are clinically accurate and culturally sensitive makes them more useful to the people reading them. Also, having the sites direct the development or at least approve the information contained in the material may improve the amount the materials are recommended to patients and that they are used.

Issue: Training should occur close to participant enrollment

It is often desired to train the users of the system prior to receiving human subjects' approval. One argument for doing this is so that they can provide feedback on the design changes and so they can get comfortable with technology.

Recommendation: We found that it is better to train the users closer to enrollment so that they don't forget how tot use the site. Also, while it is a noble thought to think users will spend the extra months getting comfortable with the technology, in reality they will not get comfortable with it until they are using it clinically. So either plan on training them twice – once for them to review the site for modifications and then again to use clinically, or demonstrate it to them on multiple occasions to get their feedback and do a single training session closer to the project actual start date.

Operational Features - Patient recruitment

The inclusion and exclusion criteria to recruit patients at each site were defined above in the *Recruitment and Operations Section*.

Team members at each site spoke directly to their patients about participation. Some sites used public announcements, brochures, or flyers for recruitment.

Patients participating from the Parshall and White Shield Health Facilities of the MHA Nation received a small gift such as a t-shirt or a coffee mug for being in this study. Those patients recruited from the Nimiipuu Health Clinic from the Nez Perce reservation were given a small gift at the time they enrolled in the program. If they continued to participate in the study they re-

ceived other gifts after two, four, and six months. The incentive program is outlined above under Clinical Deployment Section, Recruitment and Operations.

To determine if the recruitment procedures were successful, the following information will be collected throughout the recruitment period from all the sites:
- number of possible participants
- number of patients approached about participating
- number of patients agreeing to participate

Issues and recommendations
Issue: Recruitment slower than expected
At most of the sites, the actual number of patients fitting the inclusion criteria was often much less than the perceived number when the site was first asked to participate. Because of this, recruitment was much slower and the population much less than expected.
Recommendation: It would have been beneficial to ask the sites to cull through their patient records and get a firmer number of potential participants. Sites with dedicated project managers had an easier time enrolling patients from the pool of possible participants than did those sites that relied on their clinical nurses to enroll the patients.

Technical Features – Setup and Implementation
During this third year, we ran into problems with the implementation of some of the modem devices and glucose meter cables. Problems were encountered at the PBCI site with reading the data from the glucose meters. Unfortunately, these problems were difficult to recreate and it took a visit to the site and multiple calls to the manufacturer of the glucose meter and cables to identify the problems. Once the problem was identified, it took a couple of months before it was resolved because the problem was with the glucose meter cable and not our application. Once the manufacturer replaced the broken cables, the site was back up and running smoothly.

Another technical problem that was encountered and was not anticipated was the use of a modem device that would reset the time in the glucose meter if it differed from the date/time stamp in the modem server. Many patients that use glucose meters do not set the date and time in their meter correctly and this leads to many problems when they download the data for processing. So this feature by the modem device manufacturer was a great idea in principal, but because Hawaii does not follow daylight savings time (DST) caused many problems when the east coast, where the modem server resides, switched to DST.

Issue: Test technology thoroughly
All technology that is delivered to the clinical sites needs to be fully tested prior to their receiving it. It is critical to the acceptance of the system by both providers and patients that there not many distractions due to technical difficulties.

Recommendation: After our experience with the PBCI, we started having all modem devices and cables shipped to the ISIS Center first where we thoroughly tested each one before shipping them out to the site. When the site personnel need to spend time troubleshooting the technology, reprogramming modem devices or finding ways to work around technology bugs, their acceptance rate drops fast and it is difficult to win them back.

MONITORING PHASE

The monitoring Phase of this project includes Operational, Technical, Security, and Outcome evaluations. While this phase has become, evaluation of it has not. Below is information that is being collected and will be used to evaluate the monitoring phase of the project.

Evaluating Compliance with Clinical Monitoring
- frequency of blood sugar testing
- frequency of sending in BG values
- frequency of reviewing BG data and other clinical info by patient
- frequency of reviewing BG data and other clinical info by provider
- frequency of sending comments or messages

The women of the NNMC are asked to check their blood sugar readings between 4 and 9 times per day depending on the patient. Data will be analyzed for the patients by looking at the frequency with which they test their sugars compared to what they were asked to do. These values are stored in or can be calculated from the MyCareTeam database. Similarly, the frequency with which patients and providers review data in the database and message one another can be determined from the data stored in the MyCareTeam database. Since only 9 patients are currently enrolled in the study at NNMC, we have not begun analyzing the data received so far.

Treatment Changes
- number of changes in medications by care provider
- Suggested diet or exercise changes by care provider
- Number of messages sent to patient with clinical content, suggestions, or advise

The amount that patients and providers message each other, the types of messages they send and the frequency with which providers make adjustments in medications online provide an indication of how accepted the technology is and how useful each side thinks it is. This coupled with results from the patient satisfaction surveys will be used to determine the success of the technology insertion. Again, data analysis has not begun.

Assessment of Clinical Outcomes
- Change in A1c
- Change in Cholesterol measures
- Change in BMI
- Change in numbers of hypo- and hyperglycemic events
- Weight of baby at birth (for NNMC)

Diabetes outcomes are measured by the above clinical parameters. Previous studies of MyCareTeam have shown improvements in A1C, cholesterol and BP while showing a decline in BMI (Smith, Levine, et al, 2004; McMahon, Gomes, et al. 2005). It is expected that this study will show similar results. Patients will have regular lab tests and those values will be entered in the MyCareTeam secured database. We can then use the data from the MyCareTeam database to analyze the clinical outcomes of the patients enrolled. As stated above, we will look at the groups of individuals that showed the largest improvement in clinical parameters and determine the characteristics of the population as well as the actions of those patients to determine the most effective use of MyCareTeam.

Other process parameters that we will track and analyze include those associated with inserting, maintaining and supporting the technology. These include the Use of the MyCareTeam technologies, training users on the system, and the support that was required and provided.

Use of Technology
- Frequency of use
- Ease of use
- Most used features

The frequency of use of MyCareTeam by patients will be collected as stated earlier – by reviewing the audit trails maintained within the MyCareTeam application. These audit trails track when users log into and out of the system and thus how long they are engaged can be calculated. We track how often the patients engage in some of the features of MyCareTeam like exercise tracking, communicating with their providers, and maintaining their "other medications" list. These values plus a short survey on their perceptions regarding ease of use, features they like, and those they say they use most will be used to evaluate the acceptance of the technology by the patients. We have begun collecting this data on the NNMC patients who have been enrolled in the study. Data collection for NNMC will continue, and will begin for the Native Communities throughout the third year of the study.

We also track how frequently providers use the system – however, they may be more likely to use the system even if they don't find it intuitive or easy to use if their patients use it. We have started collecting data on the providers at the NNMC and will continue to do so throughout the third year. Data collection of providers use at the Native Communities will begin as soon as patients are enrolled.

Support
- Number of support calls received
- Number of bugs reported
- Number of fixes made
- Amount of time MyCareTeam was down

Enrollment of patients at NNMC began February 2005 and continued through the end of the second year of the study August 30, 2005. During that time, three support calls were received and logged. One was from a provider that forgot their password, and the other two were because the provider could not see patient data that was in the database. All three of these issues were resolved quickly.

Support logs track the numbers and types of support questions that are raised, how they are fixed, and the length of time between the support request being filed and the resolution of the problem. E-mail, telephone, and messages from within MyCareTeam are all available for providers to register technical problems or questions.

Key Research Accomplishments:
Mandan, Hidatsa, and Arikara Nation (MHA)

- Early in the year, biweekly conference call meetings were initiated between the principal investigator at MHA Nation, the study team coordinator, and Pam Angelus at the ISIS Center to monitor patient enrollment. The site was encouraged to enroll ten patients per month putting them on target to reach 50 patients by the end of February 2006.
- The study coordinator notified us in late November that as of December 6 their clinics would switch from using the Accu-Chek glucose meter to the Precision Xtra. This required a change in the type of modem device that study patients used to upload their data.
- Throughout December '05, the staff at Aerotel Medical worked to reconfigure the Tele-CliniQ modem to work with the new Precision Xtra glucose meters now being used at the MHA Nation clinics. At the same time, the team at the Poarch Band of Creek Indians started experiencing problems with their older Precision meters and cables. Recognizing that further testing would be necessary, before these meters could be fully operational at the MHA Nation, Betty Levine and the PI at MHA Nation decided to temporarily discontinue the project at MHA Nation and to lay off the study coordinator. This action was taken primarily to conserve financial resources until enrollment could start again.
- In January '06, Abbott Laboratories, manufacturer of the Precision meter, confirmed that problems existed with the glucose meter cables they sold. They stopped selling/shipping the cables and began a process of scanning and testing all of the cables they had in stock to determine which ones caused problems while looking for a new cable vendor. On March 24, 2006 we had successful completed a series of tests using the Precision Xtra glucose meter with new cables provided by Abbott and the Aerotel TeleCliniQ modem and that the study could resume. A conference call was held on April 10 with Ms. Hall-Thompson and the study nurse, Shasta Mandan for the purpose of developing a plan to restart the project and to contact those patients enrolled prior to December 2005. In order to continue the study, these patients needed to receive the Aerotel modem and information on how to use it. We also discussed a number of outstanding invoice issues that have been ongoing since 2005. We were told then that Ms. Joan Fredricks, their contracts specialist would contact use regarding the invoices. We were contacted this past summer regarding the invoices and worked with Ms. Fredericks to get them paid. It has been difficult to get the site to restart the study or to meet to discuss what needs to be done to restart the study.
- Annual continuing review authorization from the Aberdeen Area IRB was received on December 13, 2005. This approval was submitted to HSRRB on December 29, 2005 and approval was received.
- At this point, the subcontract between MHA Nation and Georgetown University has expired and we are waiting to have further discussions regarding their intentions before restarting it.

Poarch Band of Creek Indians (PBCI)
- Continuing review approval was received from Dr. Phillip Smith Chair, National IHS IRB for the Poarch Band of Creek Indians on August 31 2005. A modified telephone survey was also approved which will be used as part of the study evaluation process. The selection of Jamie McGhee to replace Annette Hick as the principal investigator for the Poarch Band site was also included in the approval from Dr. Smith and the National IHS IRB.
- Biweekly conference call meetings take place between the principal investigator and the study nurse to monitor patient enrollment at this site. The site was encouraged to complete patient enrollment by the end of February so the subjects will have a full six months to use MyCareTeam application before the project ends in August

- A total of 25 patients were enrolled in the project at Poarch Band of Creek Indians clinic in Atmore, Alabama.
- The telephone surveys were carried out by Pam Angelus of the ISIS Center.
- The study coordinator began seeing problems with patients uploading their data and noticed error messages appearing on patients' glucose meters in December. Their equipment was tested at the ISIS Center but the problem could not be easily or consistently recreated. Pam Angelus and Ming-Jye Hu traveled to Alabama in January to resolve the problems. Despite this onsite effort, the difficulties continued. After returning to Washington, we received the news from Abbott that their Precision Glucose Meter Cables had problems and that were consistent with the cable problem. The Poarch Creek site received a new order of cables on February 16, 2006 and had no further equipment failures.
- The subcontract with Poarch Band of Creek Indians expired on August 31, 2006. Once our contract modification from the US Army was received on September 6, 2006 we were able to draw-up a new contract with PBCI and it should be executed shortly.

Papa Ola Lokahi
- Numerous discussions occurred between the ISIS Center and Papa Ola Lokahi in Hawaii on how to modify the protocol and consent form based on discussions with the Native Hawaiian Health Care Systems IRB. These discussions centered around the following issues:
    1. De-Identifying of data before transmitting it to the MyCareTeam database hosted at Georgetown University
    2. Statistical methods used to analyze study data
    3. GAO Report and its relationship to this project
    4. Ownership of project supplies and equipment

- Revisions to the protocol and consent documents were completed and returned to the Native Hawaiian IRB. The IRB met on December 9 to reconsider the project for approval and they granted approval. The project also cleared the HSRRB on March 15, 2006.
- While awaiting HSRRB approval, the project team held weekly conference calls to identify alterations to the website. The following changes were made to accommodate Native Hawaiian project team: native plants and accessories were added to the images of the clinic building and reception area; the physical appearance of the clinic receptionist was changed to appear more Native Hawaiian; add Hawaiian words to parts of the site – in order to do this we purchased the software package Guava Graphics to allow us to properly accent words in the Hawaiian language.
- The Aerotel modems that will be used by the two clinics were shipped to the ISIS Center, before going on to Hawaii. They were thoroughly tested and each modem programmed in our lab. We felt that this would allow us to identify any potential problems that might occur and possibly delay the project. The Aerotel modems are designed to reset the date and time on the glucose meters based on a time zone flag programmed into each modem. However, since Hawaii does not follow daylight savings time, this becomes an issue when the rest of the country switches between standard and daylight savings time. Aerotel disabled this feature in the modems being used by the Hawaii sites. Once the updated firmware was sent to the ISIS Center, we reprogrammed all the modems and they were shipped to Hawaii.
- Two nurses came from Hawaii for training on the site. One is the head nurse from the Ke Ola Mamo clinic in Oahu and the other the nurse from Na Pu'uwai in Molokai.

- 15 patients have been enrolled between the two clinics at this time. Each clinic has agreed to enroll a minimum of 15 patients.
- The subcontract with Papa Ola Lokahi was fully executed once final HSRRB approval was received. However, that subcontract did expire on August 31, 2006. Once our contract modification from the US Army was received on September 6, 2006 we were able to draw-up a new contract with Papa Ola Lokahi and it should be executed shortly.

Tlingit and Haida
- Final project approval was received from the Alaska Area Institutional Review Board on August 31. The study team completed the Human Subjects Protection training. The training certifications and protocol were submitted to HSRRB for final approval and it was received on February 27, 2006.
- The South Eastern Alaska Regional Health Consortium (SEARHC) managed the study on behalf of the Tlingit & Haida tribes of Alaska. The subcontract to SEARHC was completed in November and signed by the proper SEARHC officials. The diabetes nurse who coordinated the study was trained at the ISIS Center on November 4.
- A total of 13 patients were enrolled in the study and the study nurse was not able to recruit any others. Discussions were had to reduce the inclusion criteria to patients with very good glycemic control – however the study team at SEARHC felt this would not really help.
- In a conference call held with SEARHC study team on July 26, 2006, the decision was made to shut down the project at their site. They did not feel that they could recruit near the number of patients originally identified. The study nurse thought the project required more of her time than she expected and the PI felt that they did not understand their patient population fully.
- As of August 31, 2006 the subcontract between SEARHC and GU expired and it will not be re-executed.

Nez Perce
- Human Subjects training certifications and the IRB protocol were submitted to HSRRB and were approved on February 14, 2006
- A full time project coordinator and part time assistant coordinator were hired during this year to manage the project at the Nimiipuu Health Clinic. They both traveled to GU for training in January 2006 and enrollment began in February 2006.
- Final approval on several protocol amendments were received this year including replacing Dr. Valerie Foxas principal investigator with Patricia Harround, FNP; addition of the study coordinators to the protocol; and several changes to the Satisfaction With Telemedicine Survey. One study coordinator resigned during the year after being elected to the Nez Perce Tribal Board. The team continues to monitor their progress and will replace the assistant coordinator if necessary.
- Twenty-nine patients are currently enrolled in the study.
- The subcontract with the Nez Perce expired on August 31, 2006. Once our contract modification from the US Army was received on September 6, 2006 we drew-up a new contract with the Nez Perce and it should be executed shortly

Wampanoag Tribe of Gay Head
  1. No further progress.

Rosebud Sioux
1. No further progress.

Mescalero
1. No further progress. They have chosen not to participate at this time.

Oglala Sioux
1. No further progress.

National Naval Medical Center
- Discussions were held with the NNMC study team to discuss strategies for increasing patient enrollment.
    o A recruitment brochure was developed and approved by the NNMC and Georgetown IRBs and HSRRB to give to potential study patients.
    o It was decided to investigate the inclusion of patients on insulin pumps – a subset of their population that they chose to exclude originally. This new feature would assist the providers by including insulin pump prescriptions for those patients using a pump for diabetes management and would require the patient to enter their insulin boluses that they administered throughout the day. A meeting was held with an Endocrine nurse at NNMC to discuss how best to implement this feature.
    o A protocol amendment was filed and approved that allows patients with only cellular phone service to be enrolled in the study. The original protocol allowed only those patients with land line phones to enroll in the project. The addition of patients without land line phones requires them to connect their glucose meters directly to their computers to transfer the glucose readings. Currently the readings are transferred via telephone modem. It was identified that a fair number of NNMC patients do not have land line telephones but do have access to personal computers and the Internet.
- Dr. Macedonia returned from his deployment in Iraq and was briefed on the progress of the study. He did not take over as PI again, but it was left with Dr. Sabi.
- To date 35 patients have been enrolled in the study. Satisfaction surveys have been administered on all enrolled patients.
- A cooperative research and development agreement exists between NNMC and GU and is currently up-to-date.

Advisory Board
- During this past year we held one Advisory board conference call and one face-to-face meeting.
- Five board members were in attendance for the conference call. The minutes from conference call are attached to this report in Appendix C.
- The face-to-face meeting was held on June 9, 2006 in Washington, Dc. This time was selected to coincide with the American Diabetes Association Annual Meeting and we had hoped many board member s would be in town attending the meeting. Four board members were able to make the meeting. Study coordinators from 3 of the sites were invited to give presentations to the board. A few outside individuals also attended. The minutes are attached to this report in Appendix D.

Reportable Outcomes:

Presentations

- o Pam Angelus attended the Diabetes Best Practice Conference at Washington Hospital Center on April 20, 2006. The conference was organized by the MedStar Diabetes Institute and Michelle Magee, MD a Sacred Breath Advisory Board member. Information regarding effective outpatient glycemic control was discussed.

- o Betty Levine attended the 1st transdisciplinary Conference on Distributed Diagnosis and Home Healthcare April 3-4 in Arlington, VA. The meeting was sponsored by IEEE EMBS society. Ms. Levine and her co-authors were Red Ribbon Winners for their poster titled "The Case for Applying the Point of Care Testing Standard to Home Monitoring Devices". The poster focused on their working connecting multiple vendor blood glucose and pressure meters to computers to retrieve the clinical data stored within the devices.

- o Betty Levine attended the NIBIB Point of Care Technologies Workshop held in Crystal City Virginia on April 11th and 12. They presented their poster titled "The Case for Applying the Point of Care Testing Standard to Home Monitoring Devices".

- o April 1, 2006, Betty Levine presented to the Capital Hill Steering Committee on TeleHealth and Healthcare Informatics in a session entitled: "Distributed Technologies for Alternate Care Delivery Sites: Community Health Centers; Home Care; Nursing Homes; and Rural Health Clinics". The presentation "IT for Chronic Illness Management in the Home " presented on the Medical Vanguard Diabetes Management Project as well as a Congestive Heart Failure Home monitoring project recently completed at GUMC.

- o We once again presented our technology at the Capitol Hill Steering Committee on TeleHealth and Healthcare Informatics' annual all-day Health Information Technology Demonstration and Discussion on Tuesday, June 6, 2006. The MyCareTeam application and more specifically the Medical Vanguard Diabetes Management sites were highlighted

Funding applied for based on work supported by this award

- a. NIH STTR Phase I: "Hypertension Software Tool to Improve Clinical Management". Submitted April 1 2006, not funded.

Conclusions:

This third year of the Medical Vanguard Diabetes Management Project saw much progress. The human subjects' requirements and subcontracting tasks have all been completed and approved for all the sites. All of our sites are now in a position to recruit and enroll participants.

We have had two set backs this year. The first being the break in forward progress with the MHA Nation of North Dakota and the second being the decision by SEAHRC to shut down the

project. As explained in this report, the switch of blood sugar monitoring technology at the MHA Nation health clinics forced a change in the technology to be used by their patients. This required a shutdown of a couple of months which we have not been able to recover from. We still try to get the site to restart and will not give up until we receive formal request from them to shut it down. Unfortunately, SEAHRC that was running the project on behalf of the Tlingit and Haida tribes of Alaska has requested that the project be stopped at their site. They were not able to recruit enough participants to make continuation feasible. The month of September was spent working with them to notify the IRBs of their decision, contact patients and return unused equipment.

The clinical personnel at each site continue to provide valuable feedback regarding modification and additional features to MyCareTeam that fit their specific clinical needs. A personalized MyCareTeam site was created this year for the Native Hawaiian clinics. This personalized site allows the patients and providers affiliated with the Native Hawaiian Clinics to feel more comfortable using the technology.

Patient satisfaction surveys have been administered to all of the patients enrolled at all the sites. Those that have been enrolled in the study long enough have completed their follow-on survey. The results of these surveys will be analyzed to determine how satisfied the patients are using the technology to monitor their diabetes and to communicate with their healthcare team. Providers give their feedback on the use of the technology through more informal means.

References:

KE Smith, B Levine, SC Clement, MJ Hu, A Alaoui, SK Mun, "Impact of MyCareTeam for Poorly Controlled DM", Diabetes Technology and Therapeutics, 2004, Vol 6. Number 6, pp 828-835

GT McMahon, HE Gomes, SH Hohne, TMJ Hu, BA Levine, PR Conlin, "Web-based Care Management in Patients with Poorly Controlled Diabetes Mellitus", Diabetes Care, 2005, Vol 28, 7, 1624-1629

Appendix A
Screen Shots of Pages changed this year

1. Outside of building for Hawaii Sites
2. Lobby, Receptionist, and Hawaiian words for Hawaii Sites
3. Direct Connect of Glucose Meters for NNMC
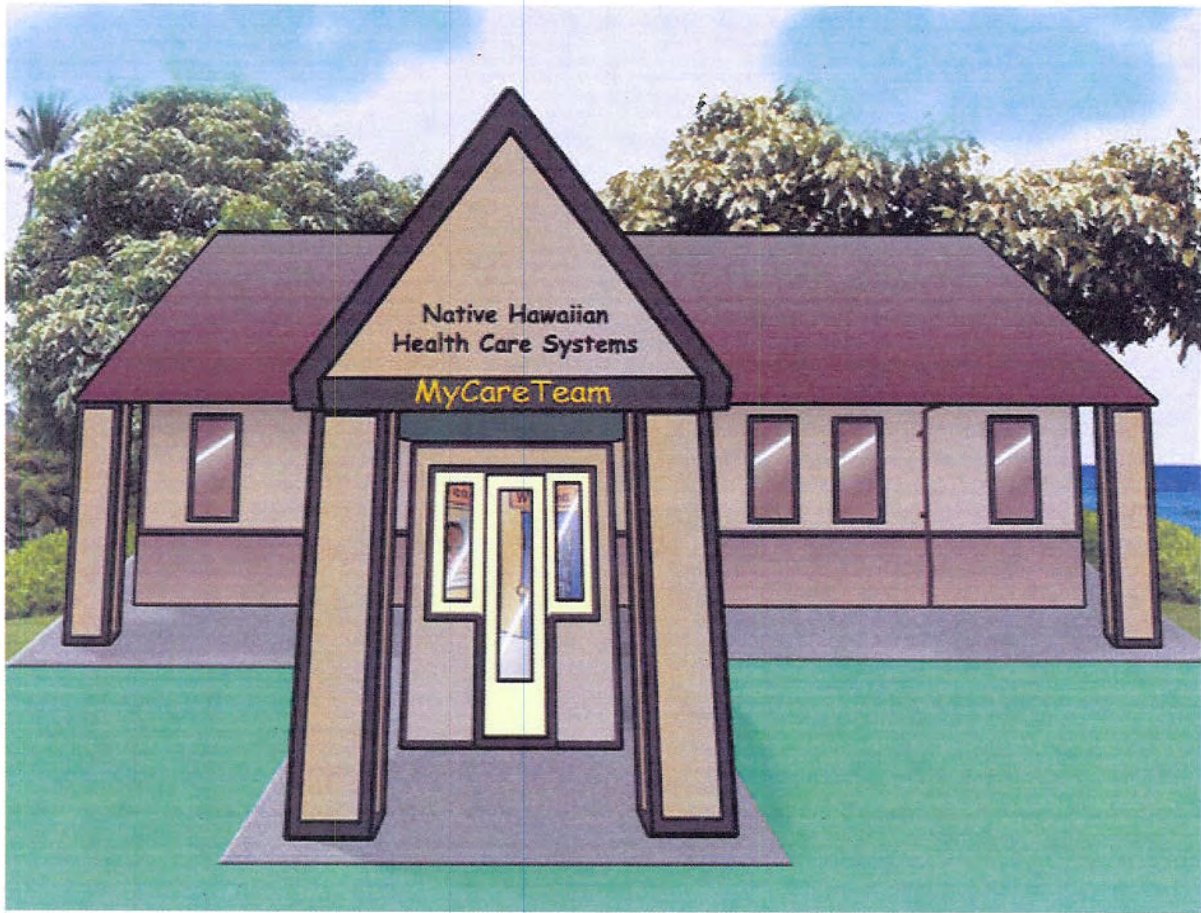
Native Hawaiian
Health Care Systems

MyCareTeam

Sponsors

Read My Meter

*Please connect the meter to the cable. Do NOT turn on the meter.

Meter Type   Accu-Check Advantage

COM Port   COM1

START   CANCEL

Done   Internet

W81XWH-04-2-0002

Appendix B
ISIS Information Assurance Policy

ISIS CENTER INFORMATION ASSURANCE POLICY

Table of Contents

1. **I. STATEMENT**

2. **Purpose**

3. The ISIS Center Information Assurance Policy (the " ISIS IA Policy") serves to create an environment that will help protect all members of the ISIS Center, their academic, commercial and government partners, and their customers and patients from threats that could compromise the privacy, confidentiality, integrity and availability of information assets and, thereby, damage their reputations, life or safety, productivity, intellectual or commercial interests, mission readiness, or financial well-being. The ISIS IA Policy recognizes the vital role information plays in the ISIS Center's activities and helps establishes means to protect information in all forms from harm. The ISIS IA Policy supplements and functions in coordination with the Georgetown University Information Security Policy ("GU IS Policy"- see Appendix A). The ISIS Center will establish a baseline information assurance program designed to protect the range of assets typically managed in its everyday work. Individual ISIS Center divisions or projects may and shall supplement the ISIS IA Policy as necessary to protect special information assets, address individual vulnerabilities or mitigate specific threats. The ISIS Center will review and revise this policy upon detecting a deficiency of policy or procedure, becoming aware of a relevant change in its academic, commercial, legal or regulatory environment, and, at least, annually.

i. The ISIS Center manages information and information assets of many types in the course of conducting its routine research and development as well as administrative work. In addition to complying with the Georgetown University Information Security Policy, the ISIS Center must develop supplementary information assurance policies and procedures to address the specific requirements of its mission, operational circumstances, information assets and business partners. The policies that follow the roles and responsibilities sections shadow the order and topics of the Security Standards and Implementation Specifications of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 because ISIS operates primarily in the health care arena, works primarily with health care partners, occasionally may function as a business associate of HIPAA covered entities and

must, therefore, demonstrate its compliance with HIPAA. Because ISIS works with partners subject to the information assurance policies of various Federal agencies such as the Department of Defense, the Department of Homeland Security, the Department of Health and Human Services and the Central Intelligence Agency, it must also demonstrate knowledge and adherence when relevant to their information assurance requirements. ISIS investigators also work with commercial partners who share proprietary information in good faith and under non-disclosure agreements. If commercial partners cannot trust ISIS to protect their proprietary information, they will not do business with us. Thus, although shadowing HIPAA, the ISIS IA Policies encompass broader requirements that protect all types of sensitive but unclassified information. If a project develops information that must become classified in accordance with Federal rules or requirements, the principal investigator must find another home for it outside the ISIS network.

4.   The ISIS IA policy contains six sections:

5.   **Scope**

6.   *Persons*

7.   The ISIS IA Policy applies directly to all members of the ISIS faculty, staff, consultants, temporary employees, volunteers and other members of the ISIS community who have privileges to create, review, alter, or otherwise use ISIS Center information assets. In accordance with the GU IS Policy, ISIS Center faculty and staff play roles with requisite responsibilities for the protection of ISIS information resources, including:

    ii.   Steward: individuals with primary responsibility for specific information resources. Stewards may or may not be the owners or creators of their information resources under their care. For example, Principle Investigators function as stewards for all information resources in their research projects even if other faculty or staff created or own them.
    iii. Users: all ISIS members function as users of and, thus, have basic responsibilities to protect ISIS information resources.
    iv.   Managers: Individuals with supervisory or management responsibilities in ISIS.
    v.   Information Assurance Officers: Individuals with administrative or technical responsibilities for ISIS information assurance.

8.   The ISIS IA Policy also addresses protection of information resources shared between ISIS members and academic, commercial and government partners. The ISIS IA Policy establishes means to protect information resources given to and obtained from partners according to its criticality and sensitivity as mutually agreed and formally documented in the data sharing agreement. Such agreements will comply with the requirements of any and all relevant local, state or Federal

regulations such as with the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

9.   ***Information Resources***

10.   The ISIS IA Policy applies to all ISIS Center information resources, including those used by Georgetown University or the ISIS Center under license or contract. "Information resources" include information in any form such as paper, electronic media or the spoken word, as well as all computer and communications equipment and software.

11.   The GU IS Policy assigns information to one of three categories depending on the level of security required, including in decreasing order to sensitivity, Confidential, Internal-Use-Only, and Unrestricted. The GU IS Policy treats Confidential and Internal-Use-Only information as Restricted.

12.   ***Confidential Information.*** This classification covers sensitive information about individuals, including information identified in the Human Resources Manual, and sensitive information about the University, including the ISIS Center. Confidential information requires a high level of protection against unauthorized disclosure, modification, destruction and use. See Appendix A, Numbers 12 to 17 for specific categories of Confidential information cited in the GU IS Policy.

13.   The ISIS Center has identified specific categories of information falling into this category that are routinely created, reviewed, altered or otherwise used in its activities, including:

   a. Individually identifiable information about research subjects
   b. Commercial, proprietary information
   c. Research information, including data and protocols, techniques, hardware or software owned by ISIS members
   d. Unpublished research reports
   e. Human resources information about ISIS faculty and staff
   f. ISIS administrative information such as budgets and financial reports
   g. Information security data, such as passwords, risk assessments, and information about security incidents

14.   ***Internal-use-only.*** This classification covers information that requires protection against unauthorized disclosure, modification, destruction and use, but the sensitivity is less than for Confidential information. Examples of Internal-use-only information include internal memos, correspondence, and other documents subject to controls established by the information steward.

15.   ***Unrestricted information.*** This classification covers information available for disclosure to any person inside or outside the University. Although security mechanisms are not needed to control disclosure and dissemination, they are still

required to protect against unauthorized modification and destruction of information.

16. ***Default classification.*** Information that is not classified explicitly is classified by default as follows: Information falling into one of the Confidential categories listed in the GU IS Policy or item 13 above is treated as Confidential. Other information is treated as Internal-use-only unless it is published (publicly displayed in any medium) by the Steward, in which case it is classified Unrestricted.

17. **II.   PHILOSOPHY**

18. The ISIS IA Policy supports the philosophy of the GU IS Policy, particularly its dedication to supporting the educational, research and public services missions of Georgetown University and its support of university policies regarding information access, acceptable use and privacy (see Appendix B and Appendix C)

19. The ISIS IA Policy seeks to ensure that all ISIS members promote the ISIS Center's reputation as a responsible research partner and custodian of sensitive information through practicing sound information assurance practices.

20. **III.   SECURITY ROLES AND RESPONSIBILITIES**

21. The GU IS Policy describes in detail the responsibilities of the primary university IA roles, including steward, user, manager, information service providers, the University Information Security Officer, Local Information Security Personnel, the Internal Audit and Management Analysis Department, and the University Counsel's Office. The ISIS Center will work with representatives of the various university offices with information assurance responsibilities as required, including but not limited to the University Information Security Officer. Four roles bear IA responsibilities in the ISIS Center, including steward, user, manager, and information assurance officer.

22. ***Stewards***

23. Stewards bear primary responsibility for protecting information resources under their care, including the following specific responsibilities:

     a. Discharge responsibilities of all users
     b. When necessary, establish security policies and procedures for information under their care above and beyond existing ISIS Center and Georgetown University information assurance policies
     c. Assign classifications and marking information for all information under their care
     d. Authorize individual access to information under their care
     e. Ensure life cycle documentation about the creation, storage, use and destruction of sensitive and other information under their care as necessary

f. Report known and suspected security incidents to their Managers, the University Information Security Officer or others as required by the situation.

24. In the ISIS Center, a hierarchy of stewardship assures coordinated responsibility through the information resource life cycle of creation, storage, use and destruction. Responsibilities include the following:

a. Principle Investigator functions as the primary steward for information created, stored, used and destroyed in his or her project.
b. Division Director functions as an information steward under three conditions, including:
   i. Secondary steward after the principle investigators for project information created, stored, used and destroyed in his or her division
   ii. Primary steward for project information created, stored, used and destroyed in his or her division in the absence or upon departure of a principle investigator
   iii. Primary steward for administrative information pertaining to the division.
c. ISIS Director functions as an information steward under three conditions, including:
   i. Tertiary steward after the principle investigators and division directors for project information created, stored, used and destroyed in the ISIS Center
   ii. Primary steward for division information in the absence or upon departure of the division director
   iii. Primary steward for administrative information pertaining to the ISIS Center.
d. Others as appointed by the ISIS Director

25. *Users*

26. All members of ISIS are "Users" of the information resources of the ISIS Center and Georgetown University. They should help protect information resources under their care or possession in whatever form they appear. The GU IS Policy (see Appendix A, Numbers 46-69 for details) lists and describes in detail the practices all GU users should follow, including:
a. Become familiar with and adhere to University policies
b. Implement basic physical security practices
c. Store information appropriately according to its classification
d. Distribute and transmission information appropriately according to its classification
e. Destroy and dispose of sensitive information using appropriate methods
f. Use appropriately created passwords to identify and authenticate themselves to computer systems. Passwords should contains at least 8 characters including upper and lower case letters, numbers and punctuation characters (where supported)

g. Ensure application of appropriate measures such as software patches, proper configurations and other measures to their computer to avoid compromise by external or internal attackers.

h. Properly configure remote access capabilities to avoid unauthorized access

i. Log off from all applications, computers and networks when finished

j. Employ antivirus and malicious code protection mechanisms

k. Comply with Georgetown University's backups and record retention practice policy (see Appendix D) and the ISIS Center's contingency policies on back-ups.

l. Report known and suspected security incidents to their information Stewards, Managers, the University Information Security Officer or others as required by the situation.

27. ***Managers (of Users)***

28. ISIS Center managers include the Director, Division Directors, faculty who supervise students or staff and administrators who supervise staff.

a. Discharge responsibilities of all users

b. When necessary, establish security policies and procedures for information under their care above and beyond existing ISIS Center and Georgetown University information assurance policies

c. Authorize individual access to information resources following the standard ISIS policies and procedures

d. Assure all users under their supervision receive information assurance training and awareness.

e. Report known and suspected security incidents to their information Stewards, Managers, the University Information Security Officer or others as required by the situation.

29. ***Information Assurance Officers***

30. In the ISIS Center, multiple people bear specific responsibility for information assurance, including the Directors and staff of both the Division of Engineering and the Division of Information Assurance and Informatics. The Director of the Division of Engineering functions as the ISIS Technical IA Officer. As a group, they ensure execution of the information security responsibilities assigned to the Information Service Providers in the GU IS Policy, including

a. Establishing security policies and procedures,

b. Conducting information assurance risk assessments,

c. Developing, implementing and evaluating information assurance risk management plans,

d. Develop and enforce ISIS security incident management and reporting plan.

e. Developing, deploying and testing the ISIS contingency plan in collaboration with ISIS faculty and staff

f. Developing, deploying and testing the ISIS security awareness and training program in collaboration with ISIS faculty and staff

W81XWH-04-2-0002

g. Coordinating physical security with the ISIS Director and other managers,

h. Designing the ISIS network security architecture

i. Implementing technical controls to protect ISIS information, computers and networks,

j. Deploying technical access controls to enforce Georgetown and ISIS information access policies, including perimeter defense and encryption of information as necessary

k. Deploying technical mechanisms for enforcing Georgetown and ISIS password policies

l. Deploying technical mechanisms for enforcing Georgetown and ISIS integrity requirements

m. Coordinating ISIS Center information assurance issues with relevant Georgetown University officials as necessary.

n. Coordinating ISIS responsibilities under special initiatives such as HIPAA.

31. **IV. ADMINISTRATIVE SAFEGUARDS**

32. *Security Management Process*

33. The Director of the ISIS Center in collaboration with the Heads of each division, the ISIS IA officers and project leads will establish a comprehensive security management process to safeguard information systems and information against sabotage, tampering, denial of service, espionage, fraud, misappropriation, misuse, or release to unauthorized persons and protect hardware, firmware, software, and information against unauthorized disclosure, destruction, or modification. By establishing safeguards and controls they will protect and maintain the confidentiality, integrity, availability, authentication, and non-repudiation of the ISIS Center information system resources and information processed throughout the life cycle, including those of research and commercial partners. Project leaders in collaboration with the ISIS IA Offices shall complete a "Project IA Specification" document for each project under their supervision. The information security management process includes four major functions, namely information security risk assessment, risk management, developing and applying sanction policies for health information security breaches by ISIS personnel and regular review of health information system activity.

34. Risk Assessment. The ISIS IA Officers in collaboration with representatives of all ISIS divisions shall organize, execute and document accurate and thorough assessments of the potential threats and vulnerabilities to the confidentiality, integrity, and availability of ISIS information and associated information systems. The risk assessment shall include evaluations of administrative and physical vulnerabilities of the ISIS Center as well as technical vulnerabilities of information systems. When selecting protection measures, the risk assessment team shall balance estimated costs of controls with projected losses from a breach as a criterion for selecting appropriate solutions. The risk assessment team shall repeat risk assessments of information and associated information systems in its possession at

regular intervals, including at least one time every three years, upon the occasion of a breach or upon a major change in system configuration.

35. Risk Management. The ISIS IA Officers in collaboration with representatives of all ISIS divisions shall develop, implement and document administrative, physical, and/or technical safeguards sufficient to reduce risks and vulnerabilities to ISIS information and associated information systems to a reasonable and appropriate level as specified by good information assurance practice and the requirements of its business partners as necessary. The ISIS IA Officers shall monitor the effectiveness and, when appropriate, revise safeguards as part of a recurring cycle of information security risk management. The ISIS IA Officers will ensure continuous assessment, implementation, monitoring, evaluation and revision of the ISIS Center information assurance posture in light of changing circumstances in its organizational, technical, and/or regulatory environment.

36. Sanction Policy. Violations of the security policies of Georgetown University or the ISIS center will be handled consistent with the applicable University disciplinary procedures. Consistent with the Georgetown University Computer Systems Acceptable Use Policy (see Appendix B), the ISIS Center may temporarily suspend, block or restrict access to information and network resources when it appears necessary for the protection of the integrity, security or functionality of ISIS Center or University resources or to protect the ISIS Center or the University from liability. The University may monitor network traffic to assure the continued integrity and security of University resources in accordance with applicable Universities policies and laws; policies and procedures are subject to Internal and External Audit review. The University may also refer suspected violations of applicable law to appropriate law enforcement agencies.

37. Information System Review. The ISIS IA Officers will ensure audit trail records from all network services and infrastructure devices are regularly reviewed for indications of inappropriate or unusual activity, including daily review of network access logs, firewall activity logs, email logs and spam, and anti-virus server logs. The Division of Engineering establishes controls to ensure audit trails are periodically reviewed for all ISIS systems, including establishing an audit record capable of tracing all network activity and actions to an individual.

38. ***Workforce Clearance***

39. The ISIS Center will comply with the policies and procedures of Georgetown University Human Resources with respect to background checks for employment and normal access to ISIS information assets.
    a. When the requirements of a specific project mandate more stringent clearance procedures, the project lead shall describe the necessary procedures and identify the project members to whom they should apply in the "Workforce Clearance" section of the Project IA Specification document.

b. For special types of information such as individually identifiable health information, the project lead will prepare a supplement to the ISIS IA Policy describing the conditions under which individual staff and/or collaborators may have access to the special information (i.e. their "need-to-know").

c. In all cases, information stewards may impose restrictions on access to specific types of ISIS information, including but not limited to project information

d. All staff must receive specific authorization from their supervisor to receive access to the ISIS LAN

e. Staff shall only obtain access to the ISIS LAN upon presenting appropriate authorization to and receiving an account from authorized IA Officers.

f. Standard and emergency ISIS termination procedures shall include a step requesting the ISIS Technical IA Officer to terminate access to the ISIS LAN.

40. *Information Access Management*

41. The ISIS Center manages information of many different types in its projects, including sensitive information such as individually identifiable personal information, proprietary information, research results, human resource and financial information about its staff, and public information such as published articles and presentations. The ISIS Center produces and owns much of this information but also safeguards information from academic and commercial research and development partners.

a. Project leaders such as principle investigators and ISIS administrators bear primary responsibility for categorizing information and assigning privileges for information associated with their projects.

b. Project leaders shall grant their staff and collaborators access to sensitive ISIS information on a "need-to-know" basis and assign only those privileges necessary to accomplish their project work tasks.

c. Project leaders shall maintain a list of individuals with access to project information including their privileges in the project archives.

42. The matrix below summarizes common types of information managed in the ISIS Center with standard role-based privileges (R=Read, W=Write, D=Delete, and A=Administrative). A project director may add or subtract privileges as warranted with appropriate documentation to the individual project's archives. Note: "Co-investigators" may include collaborators inside and outside of the ISIS Center.

Information Type	Information Subtype	Role	Privileges
All		System Admin	R, W, D, A
Confidential	Individually Identifiable	Principle Invest	R, W, D, A
		Project Manager	R, W, D, A
		Co-Investigator	R, W, D
		Project Research staff	R,W
	Proprietary	Principle Invest	R, W, D, A

		Project Manager	R, W, D, A
		Co-Investigator	R, W, D
	Research Data & Analysis	Principle Invest	R, W, D, A
		Project Manager	R, W, D, A
		Co-Investigator	R, W, D
		Project Research staff	R,W
	Human Resources	ISIS Director	R, W, D, A
		ISIS Asst Direct	R, W, D, A
		Dir of Hum Res	R, W, D, A
		Administrative Staff	R, W
	Financial (ISIS & Project)	ISIS Director	R, W, D, A
		ISIS Asst Direct	R, W, D, A
		Dir of Finance	R, W, D, A
		Administrative Staff	R, W
	Financial (Project Only)	Principle Invest	R, W, D, A
		Project Manager	R, W, D, A
	Information Systems	Dir of Engineering	R, W, D, A
		Engineering Staff	R, W
	Project	Principle Invest	R, W, D, A
		Project Manager	R, W, D, A
		Project Members	R,W
Internal Use Only	Division	Division Director	R, W, D, A
		Division Manager	R, W, D, A
		Division staff	R,W
	ISIS	Division Manager	R, W, D, A
		ISIS Staff	R, W
Public		Steward	R, W, D
		ISIS Staff	R, W
		All others	R

43. Procedures for enrolling and terminating access to the ISIS LAN.
   a. Project leaders, supervisors, division directors, or the ISIS Director shall authorize access of ISIS employees and collaborators to the ISIS LAN using the "ISIS LAN Authorization Form".
   b. ISIS IA Officers shall create and/or modify accounts on the ISIS LAN for ISIS staff and collaborators only upon receiving a completed and signed copy of the "ISIS LAN Authorization Form" from appropriate supervisors.
   c. ISIS IA Officers shall terminate access to the ISIS LAN upon receiving documented instructions from project leaders, division directors, supervisors, the ISIS Director or other authorized University official.
   d. ISIS IA Officers shall maintain a current list of individuals with authorized access to the ISIS LAN.

44. ***Security Awareness and Training***

45. The ISIS Center will develop and implement orientation, annual refresher and special role security training. As well as an ongoing security awareness campaign.

46. All ISIS faculty and staff will attend orientation and annual refresher information security training as well as any special modules required for their individual roles.

47. Orientation training will review key information security topics, including:
    a. Network architecture and components
        i. Basic structure and service of infrastructure
        ii. Technical security controls
    b. Administrative controls
        i. Information access management
        ii. Dealing with outside partners
        iii. Contingency planning
        iv. Individual good practices such as password management, virus protection, media management
        v. Implications of non-compliance
    c. Physical security controls
        i. ISIS facility controls (e.g., surveillance cameras, door locks)
        ii. ISIS workstation controls (e.g., map workstations to areas with different levels of access)
        iii. ISIS media/device controls (e.g., managing disks and backup tapes)

48. The ISIS Center will deploy security training modules for individuals with special roles, including:
    a. HIPAA privacy and security rules for users of individually identifiable patient information
    b. Policies to protect sensitive personnel, financial and proprietary information for administrative staff
    c. Security in the R&D lifecycle for information system developers
    d. Obligations to protect ISIS information for departing staff
    e. Abridged version of orientation training for outsider collaborators
    f. Others as necessary

49. The ISIS center will sponsor regular attendance of IA Officers at appropriate outside training courses in organizational and technical issues in information security.

50. The ISIS security awareness campaign will seek to promote understanding of the fundamental elements protecting the confidentiality, integrity and availability of all ISIS information assets through monthly communications highlighting a theme with an issue, slogan and explanation using multiple delivery mechanisms.

51. ***Security Incident Handling and Reporting***

52. The Georgetown University Information Security policy outlines a chain of security incident reporting from the level of individual user, to manager, to local security personnel, to Information Service providers, to the University Information Security Officer.
     a. All ISIS staff will comply with this policy by initially reporting a security incident of which they become aware to their immediate supervisor or project lead.
     b. The supervisor or project lead will report the incident to the ISIS Technical IA Officer who will forward it to appropriate University authorities.
     c. The ISIS Technical IA Officer will document the security incident in the information systems archive.
     d. ISIS staff will cooperate with authorized University officials in the investigation of any information security incident.

53. ***Contingency Plan***

54. The Georgetown University Information Security Policy assigns responsibility for developing contingency plans to the Information Service Providers of individual campuses, schools or departments. Based on the relative criticality of the integrity and availability of specific information assets, ISIS information stewards in collaboration with the ISIS Technical IA Officer will plan, implement, routinely test and revise specific measures to enable backups, emergency response and disaster recovery in the event of damage, loss, malfunction or failure of ISIS information assets.

55. Data and application criticality: All ISIS information stewards in collaboration with the ISIS Technical IA Officer shall develop an impact matrix that identifies the integrity and availability requirements on scales of high, medium and low for each and every information asset under their care.

56. Backups: The Georgetown University Information Security Policy requires establishing appropriate schedules for backing up servers and other devices containing important data, retaining copies and refreshing media. The ISIS Center has established a protocol for backing-up information stored on central servers, including
     a. Servers and Applications: ISIS maintains four running backup systems

Server	Backup
Novell Server	Arcserve 6.x Enterprise Ed for Netware
Email Server	Retrospect 6.5 for windows
Backup Server ISIS LAN	Retrospect 6.5 for Windows
Web Applications: DMZ Segment	Retrospect 6.5 for Windows

b. Process and Schedule per Server: ISIS operates a routine schedule for backups on each server, including.
   i. Novell Server: The server is backed up using a 5 day incremental backup with full backup on Friday. It uses 22 DLT 40/80 tapes at 2 tapes per week providing 3 months of backup retention before a tape is overwritten. Restores of random data [files & folders] are performed weekly. User restores performed upon request. Typical restore estimated time is 1 hour depending on the size of the data being restored. The data backed up is the shared drive, home directory and system directory on the server.
   ii. DMZ Backup: The server deploys 5 backup sets (one for each day) using a tape autoloader that holds 8 tapes at a time and is configured with a running script to rotate the tapes. There are 30 DLT 40/80 tapes at 5 tapes per week. Friday tapes are stored separately to provide 6 months of backup retention before the tape is overwritten. Restores of random data [files & folders] are performed weekly. This backup system will include the email server. User restores performed upon request. The estimated time for a typical restore [retrieval of a few files] is an hour or less depending on the size of the data being restored. The data backed up is the user email and the email server files. The system issues alerts and notifications and is monitored on a daily basis.
   iii. Backup Server ISIS LAN: The server is backed up using 2 backup sets scheduled to run on specific days and times. The system uses automated 8 tape library drive DLT 40/80 tapes providing 6 months of backup retention before a tape is overwritten. The estimated time of a backup is 3 hours depending on the amount of data being backed up. Restores of random data [files & folders] are performed weekly. User restores performed upon request. The estimated time for a typical restore [retrieval of a few files] is an hour or less depending on the size of the data being restored. There are many computers in ISIS Center configured with retrospect client software and are being backed up on a regular basis. ISIS acquired the proactive option to backup users with laptops that are not connected to the network during regular back up times
   iv. Email Backup: The email server is configured with a backup schedule and has a tape drive attached to it, backups run on a daily basis and data retention is set for a 6 months period.

57. All ISIS information stewards in collaboration with the ISIS Technical IA Officer shall establish supplementary backup plans if necessary for meeting special needs of data under their care.

58. Upon request, ISIS Technical IA Officers also backup the archives of individual users or provide them with backup devices and tapes for self-support.

59. Emergency response: the ISIS Technical IA Officer in collaboration with all ISIS information stewards shall establish procedures for responding to emergency conditions threatening information assets, including:
   a. Identifying and assuring physical access to threatened information assets only to authorized personnel during an emergency;
   b. Assuring continuity of mission critical operations during an emergency such as preparing and testing alternative processing sites at varying degrees of readiness

60. Recovery Plan: All ISIS information stewards in collaboration with the ISIS Technical IA Officer shall establish recovery plans for information systems under their care based on information asset recovery attributes, including:
   a. Identity and criticality of information asset
   b. Individuals responsible for recovery
   c. Source of data for recovery
   d. Identity and source of recovery software
   e. Identity and source of recovery hardware
   f. Communication methods during recovery
   g. Necessary supplies for recovery
   h. Transportation methods for recovery
   i. Location or space for recovery
   j. Power and other environmental requirements for recovery
   k. Documentation for recovery

61. ***Collaboration with partners outside the ISIS Center***

62. ISIS Center investigators vitally depend upon initiating, fostering and maintaining research and development collaborations with individuals and organizations outside of the ISIS Center. Mutual trust in safeguarding shared sensitive information of all types constitutes a basic condition of successful partnerships.

63. The ISIS Center has adopted a risk-based approach to sharing particular types of information with examples appearing in the collaboration matrix below. ISIS information stewards will categorize and document the sharing risk for all information assets under their care.

Information Type	Low Risk	Medium Risk	High Risk
Patient data	Aggregate	De-identified but traceable	Individually identifiable
Research data	Public domain	Published research data	Unpublished research data
Software	Open Source	Proprietary executable	Company or ISIS source code
Hardware	Low cost, mis-	Low to medium	High cost or

	sion neutral	cost, mission-important	mission-critical
Information System	Low cost, mission neutral	Low to medium cost, mission-important	High cost or mission-critical

64. On behalf of individual projects, Georgetown University shall negotiate information asset sharing agreements. All agreements between ISIS and outside investigators shall list and describe any types of information expected to be shared among the collaborating organizations as well as the obligations of each party to protect the shared information from breaches of confidentiality, integrity or availability. For high risk types of information, the agreements shall appear in writing, particularly for individually identifiable information including but not limited to health information. In principle, the agreements will commit each party to protecting the information according to good information security standards and any relevant laws such as HIPAA or the Federal Information Security Management Act (FISMA). Written agreements shall appear as attachments to the Project IA Specification document.

65. ISIS Center shall honor and include obligations to protect shared information deriving from prime contracts either when receiving or issuing subcontracts.

66. ISIS Center will not share confidential information outside the bounds of the relevant project except when required by University, regulatory agency or legal officials with appropriate authority, particularly individually identifiable human subject information.

67. ISIS Center will not share confidential administrative information except when required by University or legal officials with appropriate authority, including ISIS financial, human resource or information security information.

68. **V.   PHYSICAL SAFEGUARDS**

69. *ISIS Facility Security Plan*

70. The ISIS Center is located on 2115 Wisconsin Avenue, NW, Suite 603, Washington, DC, a conventional office building. During regular business hours the front doors to the office building remain unlocked. An electronic key system controls access to the building outside of regular business hours. The ISIS Center includes four doors, of which the main, front door provides primary entrance. The ISIS Center permits graded access to facilities and equipment on a need-to-know basis, including public, restricted and authorized personnel only access. The matrix below summarizes physical access controls to types of facility in support of the overall information access management plan:

Access	Space	Control Mechanism

Type		
Public	Reception	1.Receptionist receives, documents in log and announces all visitors when available 2. Receptionist receives all packages 3. Front door locked at all other times 4. Employed ISIS staff members receive keys to front door
Restricted	Hallways, Conference Room, Faculty and Staff Offices	1. ISIS staff escorts all visitors through hallways 2. Office doors locked when unoccupied 3. ISIS staff members shall receive keys to own office door. 4. Designated ISIS administrators shall receive master key 5. ISIS shall maintain video surveillance of hallways
Authorized personnel only	Laboratories, Computer Room	1. Laboratory directors authorize and document individual access to laboratories on a need-to-know basis 2. Laboratory doors remain locked at all times 3. Individuals with access privileges shall receive a key or access code depending on the type of lock 4. Only members of the Division of Engineering have authorized access to the computer room. 5. Computer room remains locked at all times. 6. Members of the Division of Engineering shall receive a key or access code depending on the type of lock on computer room door. 7. Maintain video surveillance of equipment of high value or containing sensitive information when necessary 8. ISIS Technical IA Officer shall document all access for repairs or maintenance to ISIS facilities as well as information assets.

71. *Information Equipment Use and Security*

72. Information stewards shall work with the ISIS administration to follow correct University procedures in purchasing, maintaining inventory and disposing of all

information processing equipment including workstations, servers, databases, and media.
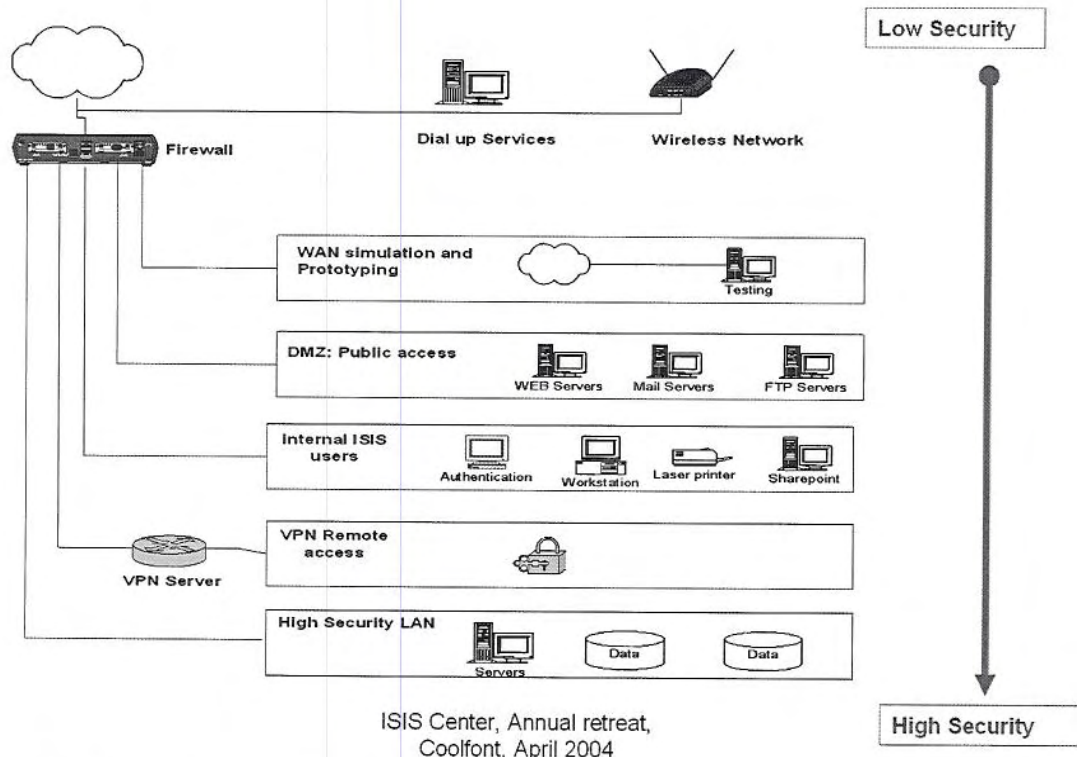
73. Information stewards shall identify and document the use for any workstation, server, or database that processes sensitive information.

74. Servers and databases processing sensitive information shall not reside in publicly-accessible or high traffic areas such as the ISIS reception, hallway, or conference room.

75. When possible avoid placing workstations processing sensitive information in publicly-accessible or high traffic areas such as the ISIS reception, hallway, or conference room.

76. For workstations that process sensitive administrative information and reside in publicly-accessible areas, implement administrative, physical and technical controls minimizing the risk of deliberate or accidental access to the information, such as sound training of workstation users, monitor screens, locks, remote data archiving and automatic logoff. Label all such workstations as "Not for Public Use." If necessary, provide clearly labeled machines for public use in publicly-accessible areas.

77. Workstations, servers and databases processing sensitive information shall reside in areas protected from damage by water, heat or other environmental hazards.

78. Information stewards shall work with ISIS administration to document and assign accountability for the movement of information equipment containing sensitive information into and out of the ISIS Center, including proper receipt of new equipment, temporary and permanent transfer of equipment outside of ISIS, data removal and final physical disposal.

79. The IA Technical Officer in collaboration with information stewards and users shall identify, implement and document procedures for properly marking, storing, cleansing before reuse or disposal IAW industry standards, and final disposing of electronic media containing sensitive information.

80. The IA Technical Officer shall periodically review documentation of physical security management, including the visitors' log, records documenting movement of information equipment and media into and out of ISIS, and media disposal to assure compliance with established procedures and identify possible breaches.

81. **VI. TECHNICAL SAFEGUARDS**

82. The ISIS Center has consistently reviewed and upgraded the sophistication of its technical information security safeguards while expanding its mission and increasing the sensitivity of its projects. When initially founded, the ISIS Center

conducted research and development on information systems without using any patient, proprietary or other sensitive information. During this era, ISIS maintained no perimeter defenses and implemented basic security controls such as username and password identification and authentication schemes. Individual researchers bore the entire responsibility for the security of their information resources. Upon launching pre-clinical trials of computer-aided diagnosis and telemedicine using patient information in various forms, the ISIS Center began developing centralized approaches to information security based primarily upon technical controls, including its initial effort at perimeter defense, a single interface firewall that isolated the ISIS LAN from the Georgetown University LAN and, later, Virtual Private Networks (VPNs) to provide secure remote access for transmitting sensitive data. Having expanded the range of its projects to include a variety of types of sensitive information, the ISIS Center, again, is upgrading its security architecture to include six interfaces that create network segments with increasingly stringent access and transmission security controls. Although project and divisional information stewards retain important roles in the ISIS information assurance program as outlined in the preceding sections of this policy, their work depends and builds upon a centrally planned, implemented and evaluated organizational and technical security plan that seeks to protect ISIS information assets as well as demonstrate compliance with regulatory requirements such as HIPAA, FISMA and the IA policies of its academic, commercial and government partners.

83.   *The ISIS Security Architecture*

84.   The following graphic illustrates the distribution of ISIS's firewalled segments:

Low Security

High Security

Firewall

Dial up Services

Wireless Network

WAN simulation and Prototyping

Testing

DMZ: Public access

WEB Servers   Mail Servers   FTP Servers

Internal ISIS users

Authentication   Workstation   Laser printer   Sharepoint

VPN Remote access

VPN Server

High Security LAN

Servers   Data   Data

ISIS Center, Annual retreat,
Coolfont, April 2004

85.   *Interface Descriptions*

Each interface manifests specific characteristics and performs specific purposes, including:

a.   Segment 1: High Security segment. (Security Level 100)
This segment bears the most sensitive ISIS information with the highest protection requirements and, thus, requires the most stringent access control rules. Specific rules are configured detailing which hosts are allowed access to specific services residing on this segment. Four SQL servers and one Oracle server exist on this subnet. Identified users with proper privileges in the DMZ, ISIS and VPN subnet will access one or more nodes on the inside interface, including the eHealth and Biodefense groups both of which manage individually identifiable data in their research.

b.   Segment 2: ISIS-VPN Router segment (Security Level 90)
This segment provides secure, remote access to, and transmission of certain bodies of sensitive information, including individually identifiable information. Access to this segment is limited to remote users with proper privileges and client software configuration.

c.   Segment 3: VLAN 77. ISIS user segment. (Security level 80)
95% of the ISIS users are currently on VLAN77. This VLAN supports approximately 50 workstations, a Novell Server and multiple printers.

d.   Segment 4: VLAN 544. The ISIS DMZ segment (Security Level 80)

W81XWH-04-2-0002

The DMZ segment contains all hosts providing public services to users on the outside of the firewall.

e. Segment 5: Prototype Segment.

This is a test segment, which does not contain sensitive data. ISIS will configure rules to provide access to workstations in this segment to specific hosts from the outside and other segments served by the firewall. F. The outside Interface (Security Level 0):

This interface functions as the outside interface for the firewall with a security level of 0.

Wireless Access point. This wireless access point is in the non- protected segment allowing access to the Internet and web resources to ISIS visitors and users roaming around the office. Devices on the wireless network are considered outsiders and have no access to other segments with higher security levels unless if used with VPN clients with proper configuration and credentials

g. IPX traffic IPX (Novel) traffic bi-passes the FW and goes directly to 2115-RTR1. This server is part of the NDS replica ring and the Georgetown tree; it is intended to stop the usage of Novel server and services.

86. *Auditing*

87. The ISIS Center is actively monitoring logs and access to the network. We are using a CISCO ACS server to authenticate remote users accessing the network with VPN clients. The ACS server provides authentication, authorization, and accounting (AAA) of user sessions to an AAA server. The server checks who can log into the network from wired or wireless connections and what privileges each user has in the network. We maintain one year login information that includes attempted and failed logins and successful logins. The logs also show user names, date and time of login and the originating IP address of the machine they are using to access the network.

88. Microsoft Active Directory: We will monitor and log AD once fully migrated.

89. Firewall monitoring: We deployed a Cisco Syslog server. The Syslog server is active and collects log messages from the PIX Firewall. The firewall constantly sends messages to Syslog server to document the following events:

    vi.   Security: dropped packets
    vii.   Resources monitoring
    viii.   System: console logins/ logouts and firewall reboots
    ix.   Accounting: bytes transferred per connection

One year of logs is stored to the Syslog. The PIX Firewall provides seven different logging levels: Emergencies, Alerts, Critical, Errors, Warnings, Notifications, Informational and Debugging.

Syslog is monitored on a daily basis for suspicious activities. Special attention is paid to Emergencies, Alerts and Warnings.

90. Auditing shared resources: for information systems shared between ISIS investigators and outside collaborators, the MOA will include requirements about who will monitor, document and review system events.

91. ***Authentication***

92. The ISIS Center requires username and password for identification and authentication into the ISIS LAN, the VPN and information systems using the Active Directory authentication system.

93. ISIS users shall implement safe password practices, including:
    a. When creating passwords, use
        i.   Length of eight or more characters
        ii. Combination of letters (upper and lower case), numbers, and special characters
        iii. Include at least one of each character type.
    b. Change the password every 90 days.
    c. Do not share their passwords
    d. Contact the Technical IA Officer when suspecting their password has been compromised.

94. ***Integrity***

95. The ISIS center maintains up-to-date subscriptions to antivirus software, loads it into new workstations, and regularly reminds users to download updates, particularly during virus scares. The email server automatically scans messages for virus detection and deletes infected files.

96. The ISIS Center provides integrity checks for transmissions using the VPN network.

97. The ISIS Center is investigating implementation of an intrusion detection system as part of the upgrade of its perimeter defense

98. ***Encryption***

99. The ISIS Center provides encryption for incoming transmissions using the VPN network for designated users.

100. ISIS users shall transmit confidential information over the Internet only using the VPN network. ISIS Center works with individual users to enable encryption of confidential outgoing transmissions when requested.

Appendix C
Minutes from Advisory Board Conference Call

Sacred Breath (aka Medical Vanguard Diabetes Management)
Advisory Board Conference Call

Date: February 3, 2006
Advisory Board Members Present: Chairperson, Marjorie Mau, Michael Ackerman, Nicole Johnson-Baker, Bette Keltner, John Scott
Advisory Board Members Not Present: Tex Hall, Chris Macedonia, Michelle Magee, Sam McCraken, Buford Rolin, Paul Tibbets, Lorraine Valdez
Georgetown Personnel: Betty Levine, Pam Angelus
Others: Carrie Gould-Kabler

1. Introduction
   - Betty Levine thanked everyone for participating in the conference call and outlined the agenda for the meeting.
   - Dr. Mau asked that minutes of the meeting be taken and circulated to all Board members.

2. Status Update – given by Pam Angelus for each of the six study sites
   - **Poarch Band of Creek Indians – Atmore, Alabama**
     1. March 2005 – all IRB approvals completed
     2. October 2005 – first patient enrolled
     3. Personnel issues delayed start of study – PI resigned, tribe unsuccessful at hiring a designated study coordinator. Diabetes clinic case manager is currently working half-time as study coordinator.
     4. 20 patients presently enrolled, IRB approved for 50 patients
     5. Recently problems arose with defective glucose meter cables. ISIS Center working with manufacturer and study nurse to resolve the issue. Patients are continuing to collect and transmit data despite the problems.

   - **Mandan, Hidatsa and Arikara (MHA) Nation – New Town, North Dakota**
     1. June 2005 – all IRB approvals completed
     2. September 2005 – first patient enrolled
     3. 10 patients enrolled through December 2005, 5 of whom did not meet inclusion criteria. Of the 5 remaining patients, 2 have requested to be dropped from the study. IRB approved for 50 patients.
     4. Limited number of patients enrolled because the coordinator's access to patient records is restricted by HIPAA regulations. Coordinator must rely on clinic personnel to identify appropriate patients for enrollment. Also, study coordinator has limited knowledge about diabetes and conducting research projects.
     5. December 2005 – the MHA clinics changed glucose meters and the new meters were incompatible with the modems being used for the study. Presently, modems that are compatible with the new meters are available, however, the same cables, used by the Poarch Band of Creek Indian's clinic, are also used with this new meter. Patients have been notified that the study and the study coordinator are temporarily on hold until the equipment problems are resolved by the glucose meter manufacturer.

   - **Nez Perce Tribe – Lapwai, Idaho**
     1. June 2005 - received local IRB approval, currently waiting for Army IRB approval (complete application submitted 1-17-06).
     2. January 2006 - study coordinators (1.5 FTE) completed training at the ISIS Center.
     3. IRB approved for 40 patients

4. Modems and meters have been thoroughly tested and no problems are anticipated.

- **Tlingit and Haida Tribes of Alaska – Juneau, Alaska**
  1. August 2005 - received local IRB approval, currently waiting for Army IRB approval (complete application submitted 1-19-06).
  2. Project administered through South East Alaska Regional Health Consortium (SEARHC) Juneau Medical Center which provides outpatient services for these two tribes.
  3. November 2005 – study coordinator (clinic's diabetes educator) completed training at the ISIS Center.
  4. IRB approved for 50 patients
  5. Modems and meters have been thoroughly tested and no problems are anticipated.

- **Native Hawaiians - <u>Na Pu`uwai</u> - Kaunakakai, HI and <u>Ke Ola Mamo</u> - Honolulu, HI**
  1. December 2005 - received local IRB approval, currently waiting for Army IRB approval (complete application submitted 1-25-06).
  2. Project administered through Papa Ola Lokahi – Honolulu, HI
  3. Per their request, study personnel will be trained by the ISIS Center in Hawaii.
  4. IRB approved for a total of 30 patients
  5. Modems and meters have been thoroughly tested and no problems are anticipated.
  6. Modifications to the MyCareTeam site are underway at the request of the project team. The modifications will make the site more culturally appropriate for the Native Hawaiian population.

- **National Naval Medical Center – Bethesda, Maryland**
  1. January 2005 – all IRB approvals complete
  2. February 2005 – first patient enrolled
  3. All study participants are pregnant women with either type 1, type 2 or gestational diabetes followed at NNMC.
  4. Project issues – PI deployed to Iraq soon after enrollment started. NNMC is a teaching hospital where patients primarily interact and are seen by residents in training. Consequently we have not had as much cooperation from the clinical providers as we would have liked.
  5. 17 patients currently enrolled, IRB approved for 40 patients.
  6. No equipment problems have occurred and none anticipated.

3. Sustainability
   - Betty Levine updated the board members about the current status of the commercialization effort. The company commercializing the MyCareTeam application has agreed to offer the service to any participating community at a reduced cost when the Sacred Breath project ends.
   - Since the communities involved initially asked Georgetown personnel about their own ability to continue the use of the technology, assuming it proved successful, after the completion of the study, GU personnel would like the Advisory Board to provide guidance on how this might be accomplished.
   - Bette Keltner provided some insight noting:
     1. Vehicles for funding this type of technology or clinical tool are different for each community
     2. Funding may rely on 3rd party payment dominated by federal funds
     3. This may differ depending on whether tribes are compacted or contracted

- Marjorie Mau stated that the sites may not have used the software long enough to be able to determine its success, therefore a discussion of sustainability may be premature. Also, the following items need to be considered:
  - Technical aspect, technical support, problems with equipment may skew how the sites and patients responded to the technology
  - Where the data is stored may also be a concern to some sites, limiting their willingness to use this technology as a clinical tool
- John Scott noted that these types of technology are the wave of the future and the experience of having done this might be considered a good outcome by itself for the different sites.

4. Next Meeting
  - We proposed holding the next Advisory Board meeting around the American Diabetes Association Annual Meeting June 9-13 in Washington, DC
  - Nicole Johnson-Baker mentioned that June 9th might be the best day since the ADA may not open the meetings on this day to everyone. And thus there may be less conflict with scientific sessions
  - At Marjorie Mau's suggestion, questions will be circulated to the advisory board members prior to the next meeting so that some thought can be given to them prior to the meeting.
  - Members from each site may be invited to present their experiences to the board

Appendix D
Minutes from Second Advisory Board Meeting

In attendance:
Advisory Board members: Marjorie Mau, Michael Ackerman, Bette Keltner, Nicole Johnson-Baker, Mark Carrol (for Lorraine Valdez)
ISIS members: Betty Levine, Pam Angelus, Seong K. Mun, Mary Lou Ingeholm, Ming-Jye Hu, Maggie Fang, Inyoung Choi, Mihai Dorobantu, Cherrel Christian
Sacred Breath Site Reps: Donna Johnson, Jaci McCormack
Department of Defense Rep: Robert Read
MyCareTeam, Inc. Rep: James Mingle
Georgetown University Rep: Scott Fleming

Opening Remarks

Opening Remarks were made by Seong K. Mun. He discussed how the ISIS Center has been involved in Diabetes and technology for a number of years. He talked about how the A1C value is a great surrogate marker for determining outcomes in diabetes research making for scientifically valid experiments. Congressional funding started the Medical Vanguard Diabetes Management Project, aka Sacred Breath, and is managed by the US Army. He mentioned that there are peer reviewed published articles that validate our technology. Dr. Mun mentioned that we are seeking guidance from the Advisory Board as to how resources and efforts should be prioritized so that we can be most helpful to the diabetes community.

Agenda Review

Dr. Mau went over the agenda (See Below) and expressed that she was excited to hear how the sites were progressing. She expressed how working in these communities is a unique process, how each community needs to work through things with their own processes and on their own time.

Status Report

Next Betty Levine gave a status report for the entire project. The Aims of the original proposal are:

1. Improve the effectiveness of diabetes management for gestational diabetes patients and adult patients in Native American communities

2. Study an effective process for inserting diabetes management technology into existing clinical programs in diverse communities

3. Not focused solely on clinical outcomes – more on acceptance of the technology and its adaptability to different cultures

She explained how this project is more about identifying if technology that was proven successful in managing diabetes with other groups could be adapted for and applied to these communities with similar success. Therefore the project is not solely a clinical outcomes study but also a study in process insertion.

The initial eight participant communities included:
Mandan, Hidatsa & Arikara Nation – Three Affiliated Tribes, New Town, North Dakota
Poarch Band of Creek Indians, Atmore, Alabama
Nez Perce Nation, Lapawai, Idaho
Chilkoot Indian Tribe, Haines, Alaska
Rosebud Sioux, Rosebud, South Dakota

W81XWH-04-2-0002

Mescalero, Mescalero, New Mexico
Wampanoag, Aguinnah, Massachusetts
Papa Ola Lokahi, Honolulu Hawaii
National Naval Medical Center, Bethesda, MD

The Chilkoot declined to participate and the Tlingit and Haida Tribes of Juneau Alaska were substituted in their place. The Wampanoag, Rosebud Sioux and Mescalero also declined to participate but no other tribes were substituted. By that time, we realized that it was going to be more difficult than expected getting through IRB approvals and getting the projects started so we chose to concentrate on the committed sites instead.

The Georgetown Team consists of Seong K. Mun, director of the ISIS Center and Principal Investigator for the project, Betty Levine – Division Head for eHealth and Telemedicine and overall project manager, Pam Angelus – compliance officer and project coordinator, Ming-Jye Hu, Maggie Fang, Mihai Dorobantu software developers, Inyoung Choi in charge of the evaluation piece of the project and consultants like Jim Grigsby who also provide assistance with the evaluation piece.

The biggest challenges faced by GU personnel so far include:
- Commitment from clinical personnel at the sites
  - Study nurse would be involved, but difficulty getting physician to work with the nurse or the tech
  - How does one get the clinical personnel involved and interested enough to use the site with their patients?
  - It is difficult to get them to understand why this could be better for their patients
- Recruitment
  - So far, recruitment has been much more difficult than anticipated.
  - How does one recruit from groups that may not feel comfortable with or may not have participated in many research studies
- Orienting study coordinators to research process
  - It is difficult to get the study coordinators to understand the IRB process and that once the protocol has gone through IRB process why everything needs to be followed exactly as laid out in the protocol
- Distance
  - Initially GU personnel traveled to all sites and worked closely with study personnel to setup the project
  - Cost of travel and time was always in the back of their minds so they did not make as many trips as they probably should have
  - In hindsight, being more visible at the sites might have helped to encourage the sites and work through some of the issues more quickly

The project Schedule is:
- Project began September 2003
- No-cost extension received September 2005
- Project scheduled to end September 2006
- Request to continue until September 2007 was submitted
- Additional funding requests will be made to congressional supporters
- Discussions are beginning with each site to determine their level of interest in continuing with the project

The future efforts of the GU group working on Sacred Breath are to design a module that manages hypertension as well as the diabetes module has worked. Also, they will continue to keep the site fresh, adding new content and new features as the needs arise or the features are identified. Lastly, Betty Levine explained that GU has entered into a commercial licensing agreement with MyCareTeam, Inc that is new for ISIS and could be a mechanism to allow those sites that find the technology useful in managing their patient to continue to use it at a low cost after project funding has ended.

Site Descriptions
National Naval Medical Center (NNMC) – Cherrel Christian
Next Cherrel Christian gave an update on what is happening with the pregnancy and diabetes group at the National Naval Medical Center. Cherrel was initially brought in as an expert in diabetes; she is a certified diabetes educator.

Recruitment Efforts:
The project began at NNMC in February 2005 and at the time of the meeting 25 women had been consented and followed in the program. The goal is to get 40 women involved. These women either have gestational diabetes or are pregnant but also have preexisting type 1 or type 2 diabetes. Of the 25 women consented, two delivered their babies before sending in data and one withdrew. Four are currently active and 19 completed the study.

The recruitment efforts included presentations to house staff and nurses before and after the study began; the gestational diabetes classes held each week for newly diagnosed women, and through study brochures distributed throughout the complicated OB and Gestational Diabetes clinics.

Project Team:
The team at the NNMC consists of Dr. Sabi – principal investigator, 2 attending physicians, the Complicated OB and Gestational Diabetes residents, 2 nurses, a registered dietitian, and Cherrel – diabetes educator and study coordinator.

What was Easy:
The easy parts for the NNMC group has been identifying patients who fit the study criteria; working with the staff although they were concerned with increased workload; the high level of technical knowledge of participants and physicians; most individuals in the Armed services are comfortable communicating online because email is used to communicate with deployed colleagues, family members, and others.

What was difficult:
One of the biggest challenges faced at NNMC was staff turnover. Because NNMC is a military installation, people get deployed even our Principal Investigator got deployed. There was always someone identified to take over, but it usually meant bringing their own ideas and ways of doing things to the project. The gestational diabetes clinic had just started when Sacred Breath was beginning which meant that we should have a larger pool of possible participants.
All military personnel and dependents living in the greater DC area who are pregnant and have diabetes get OB care at NNMC regardless of the distance they have to travel. GDM classes were held at NNMC which also provided a pool of participants to recruit from.

The challenges include the war in Iraq – Dr. Macedonia, the initial PI was deployed, the increase workload of all staff not deployed during times of deployment, getting the medical staff to communicate directly with patients via the system since they are used to calling the patient, or

waiting until the next clinic visit to discuss issues with the patient. Insulin pumps are becoming more common among women seen at the complicated OB clinic at NNMC. Initially the providers did not want to include these patients in the study – however as the project progressed they saw this as a missed opportunity and now want to include them. We have many challenges implementing the insulin pump screens in a way that is useful for the NNM personnel. There are a lot of adjustments with insulin pumps that need to be captured, making the user interface screens user friendly has been a challenge. Also, NNMC staff was also concerned that this project would lead to double charting (having to keep a paper chart and an online record). We adapted the site such that information was printed on NNMC approved forms that could be inserted into the patients paper chart.

NNMC personnel have seen an improvement in adherence by the participants. One woman who would never right down her blood sugars in table form (had a learning disability) found that when using the system, her husband could help her upload the data and the care providers got far more information from her that was used to keep her sugars under better control.

Adjustments to the Site:
One adjustment to the application that was made specifically for this population was to allow the participants to directly connect their glucose meter to their computer and transfer their blood sugar readings directly. Many of the participants do not have land-line phones and therefore the modem technology we were using to transfer the data from the glucose meter to the database would not work. Since this population has a high level of technical knowledge, this did not lead to any problems.

Technical or equipment problems:
None

Incentives:
None

In Summary:
Another benefit seen by the program was that it reduced the number of times patients had to come to the clinic and allowed the nurse to more readily get the patients blood sugar readings without having to track the patient down by phone and write up the individual readings.

Questions and comments posed to Cherrel:
1. Cherrel was asked how many patients were approached to participate.
   a. About 150 potential participants were approached and 26 had enrolled.
2. Did participating program help make the long distances easier?
   a. It was helpful – instead of having to talk to Susan they could send them in more quickly. Instead the mom comes every week they could come once every 2 or 3 weeks
3. We were asked to describe the surveys.
   a. All participants were surveyed twice while they were enrolled in the study; once 2-4 weeks after enrollment and then again right before they delivered their babies. Twenty statements on the survey are about:
      i. the use of the website
      ii. whether they learn from the information on the site
      iii. how they like communicating using the website
      iv. which features they use most often

  v. demographic information: education, where they use website (home, school, community center), what else they use the internet for
4. Cherrel described the split in the diabetes world between endocrinologists and obstetricians, often women in a pregnancy clinic are seen by these providers for the first time
5. It was pointed out that the study is a bit disjointed at NNMC because the residents are on the complicated OB and gestational diabetes rotations for 6-8 weeks – so we are constantly training new residents in the use of the system. The nurses are the ones that use the system most frequently and it is left to them to prod the residents to use the system

Poarch Band of Creek Indians (PBCI) – Donna Johnson
Recruitment efforts:
Donna Johnson, the study nurse for the PBCI project presented the status of their project. Enrollment began in October 2005 and they currently have 20 patients enrolled into the study. They were hoping to enroll 50.

Patients were recruited by reviewing their diabetes registry and identifying those that fit the criteria. These patients were contacted and the study explained to them. Those that agreed to participate met one-on-one with Donna to be trained in using the system. This was a stressful process for Donna because of the turnover in staffing during this time – the loss of their clinic director and the physician.

Project Team:
Their team consists of Donna, the study nurse, who recruits, enrolls and follows all the patients in the study, a technical support person, and their clinic director. They have been trying to get their physician and nurse practitioner involved but they are new and it has not been easy.

What was Easy:
There was not much that was very easy for PBCI initially. Technical support at the ISIS Center was always available to them and the well written protocol allowed them to enroll patients and carry out the study once patients were enrolled. However, the challenges at start up were big.

What was Difficult:
The IRB process took a long time and getting all the paperwork completed was much longer than anyone anticipated. The modem technology used to transfer the reading from the meter to the database came from Israel and when it arrived the firmware had to be upgraded. Thankfully their technical support person was able to upgrade all the devices before they were given to the patients. The equipment problems did not end there. The cables connecting the glucose meter to the modem was also problematic. The manufacturer recalled the cables and that delayed the study a few months. Unfortunately, many cables had been given out already and therefore led to frustration on the part of the participants as well as the clinical staff. A lot of time was spent by Donna and her technical support person, as well as ISIS technical support debugging the cable problem. A site visit was made by ISIS personnel to help debug and fix the problems because not all the problems could be recreated at the ISIS Center.

Computers were purchased with the intention that they would be placed in public areas to be used by participants who did not have easy access to a computer. However, placement of those computers became difficult. Finding safe and secure locations that would allow the computer and also had appropriate Internet connectivity was difficult. It ended up that one computer was placed in the senior center and the other four remained in the clinic.

Adjustments to the Site:
There were no major modifications made to the web site for PBCI.

Incentives:
Incentives per se were not used to encourage participation. With increased staffing, Donna felt she might have had better success encouraging participation by those enrolled or even enrolling more patients. Also some patients required a lot of prompting to get them to send their readings into the site and review the data online. However, some of their patients really did embrace the system and enjoy using it and feel that they have gotten a lot out of it. Potential reasons why it has been difficult to get people to participate include:
- Cultural considerations
- Depression
- Overwhelmed patients
- Educational limitations
- Distrust of technology
- Wrong generation perhaps – most of the patients are of an older generation

In Summary:
The ISIS Center personnel took over administering the surveys to avoid any conflict on the part of the surveyor.

Donna's thoughts on the project as a co-investigator;
- MyCareTeam is a good resource
- Patients who have used the program to the fullest have expressed that they really enjoyed it
- Patients and the health clinic are already doing a good job of self management of blood glucose and are managing well
- They will continue to follow the patients enrolled in the study

Questions and comments posed to Donna:
1. Robert Read asked how many tribal members have diabetes.
   a. Three with type 1 diabetes and 220 with type 2.
   b. Donna thought if they had lowered the HbA1C requirements to less than 7 then more people would have qualified for the study
   c. Michael Ackerman pointed out that if the A1C level were reduced to below 7 then those individuals are considered in control already and the system may not have been seen as helpful
2. Robert read asked where the computers were that had not been installed for the patients. Donna explained that some were still in their boxes.
3. Someone raised the question "How do you see the women who have gestational diabetes that is hard to control wanting or desiring the use of tech?"
   a. Donna answered that they are not following patients with gestational diabetes at PBCI.
   b. Cherrel responded that moms like that they can communicate with the dietician about what they can eat; as an educator she likes to talk to the moms; encouragement helps with their confidence; the women with gestational diabetes often want to know if they've done something wrong that led to their getting gestational diabetes, and many are relieved to learn more about it through the site.
   c. Donna asked if Cherrel thought that pregnancy was an incentive. Cherrel said yes, pregnant women with diabetes want to do everything to have a healthy

baby (all women do); keeping their blood sugars in control mean they will have a better delivery outcome

4. Betty Keltner expressed the belief that inspiration leads to better outcomes is not always the case; note on the sense of generalizability of the project – the ultimate purpose is to improve patient outcomes and the deleterious events. She then asked how we see it working for improving birth outcomes. If on a priority scale of the 5 things you could do for your community and having to show a result, how is this tool going to be able to achieve this act?
   a. Betty Levine explained about the study completed at the Boston VA on adults with type 2 diabetes resulted in a 2% drop over a year in HbA1C for those who sent in data regularly

5. Bette Keltner then mentioned that the question is about bridging the gap for people who live in really isolated circumstances, are we approaching this by using what we know? A smiling face is an expectation, where are we on this continuum of using this tool that we think is useful?
   a. Dr. Mun responded that yes the Boston study has shown a very good outcome, but certainly technology provided a role in that study and other conditions came together to make it successful, so we need to find what are those other conditions which we are seeking to discover in this study.

6. Cherrel Christian commented that when it comes to diabetes management its time and attention (both of provider and patient) that leads to improved outcomes; even with patients labeled as non-compliant, no patient sets out to do something harmful; the patient is going to meet his goal, whether or not that is the same as the educator's goal; technology lets the provider communicate more often with the patient; a patient with diabetes sees their provider normally every 3 months in the real world; being able to see those blood sugars would help providers (like if the patient's blood sugars aren't looking good); telephone tag is a barrier; you can use this to increase time and attention; any encouragement offered by the system can help; because of the nature of diabetes the time and attention piece is what this is going to help.

Nez Perce, NiMiiPuu Health (NMPH) – Jaci McCormack
Recruitment efforts:
Jaci McCormack, the study coordinator for the project at NiMiiPuu Health, presented their status update. NMPH serves the health care needs of the tribal members of Nez Perce and their descendants and families. There are approximately 3,750 patients served at NMPH. NMPH has 2 clinics located 62 miles apart on the Nez Perce Reservation in North Central Idaho.

Patients were identified as eligible for the project by reviewing patient charts in the NMPH electronic diabetes registry. Potential participants were then contacted by telephone to see if they were interested in participating. A display board describing the project was erected in the clinic lobby. Fifty patients qualified for the study and twenty-nine enrolled. Two patients have withdrawn.

Project Team:
Their project team consists of Jaci, the project coordinator, 1 nurse practitioner, 2 physician assistants, 2 nurses, a registered dietitian, and a diabetes educator. There has been high staff turnover since the start of the project including new providers hired, staff members taking extended leave, people being transferred and others resigning.

What was Easy:

Interacting with the study participants has been easy for Jaci, especially when they are excited about the study. She also found it easy to setup the incentive program. They are a sports' crazed community, so while it was a bit difficult to decide what incentives to use. She decided on an affiliation with Nike Corporation which will be discussed later.

Jaci found being excited about the study easy since she felt that the decision the clinic was taking to adopt the technology was the right decision. While clearing the glucose meters of existing or bad data was hard as was the initial programming of the modems, she was confident of her ability to use the technology and support the participants and providers with downloading their data and navigating the web site.

Because of the positive feedback she received from the participants and the providers, Jaci found it easy to encourage others to use the site and to download their readings.

What was Difficult:

Dealing with the IRB and the time that was required was very frustrating.

Recruitment was not always easy since there is a distance of 62 miles between the two clinics from which she was recruiting. It was also difficult to connect with working people because of the different hours they work – especially those working for the casino.

It was also difficult to arrange times to train the providers because of their busy schedules. To facilitate the provider training, Jaci would schedule a patient appointment with the provider and use that time to train them on the site. Once the providers were trained, keeping them on track to review the patient data takes much of Jaci's time.

Adjustments to the Site:
Initial inquiry was made to whether it was possible to use a sliding scale for insulin prescribing.

New exercise options were added to the exercise log book to simplify patients tracking their level of exercise.

The ability for them to submit a diabetes activity calendar that would be posted on the lobby bulletin board is in place.

Technical and Equipment Problems:
Problems were encountered getting new computers installed, and connected to the NMPH network after ordering them for use by project personnel. A separate Internet line was installed in the clinic for the patient computer. The other problem was finding out the hard way that there is a difference between analogue and digital telephone lines.

Incentives:
Patients who attended an information session on the project were given fight diabetes car magnets.

Once they agree to participate in the project and are enrolled, they are eligible for a step-program for receiving incentives.

The first time a participant downloads their readings after enrolling, they receive a pedometer.

If a participant downloaded two times in the months of May and June and checked the website once per month they received a Nike T-Shirt with the Diabetes Program symbol. If a participant checked their blood sugars at least 6 times per week for at least 4 weeks (the 4 weeks did not have to be consecutive) then they receive Nike running/walking shoes from Nike.Net. This was arranged through Sam McCracken.

Lastly, after completing the study, patients will receive a check for fifty dollars.

In Summary:
They were slow getting started due to the IRB issues and the slowness in setting up the computers.

At approximately 4 months into the study, participant and provider feedback is positive.

Patient and provider involvement continues to grow.

Statement from Roberta Carr, a provider using the system: "...it's a great way to communicate with patients without requiring them to come to the clinic every time."

Statement from George Goldner, a participant in the study: "I'm testing my blood sugars a lot more often now that I'm in that program."

Comments from some of the surveys that were completed:
- "It's a faster way to contact my providers – I usually have an answer by the end of the day." May 2006

- "It has motivated me to check my blood sugars. I like seeing the logbook with green numbers." May 2006

- "My family is drinking more water now instead of juice after getting information from the website." I learned how I can go to Disneyland and still take care of my diabetes." June 2006

Questions and comments to Jaci:
1. Cherrel mentioned that she like the way Jaci stepped the incentives
   a. Jaci answered that after people received information about the step program she received more phone calls regarding whether or not they were following the step program and wanted to make sure they were
2. We will look into whether others can have access to the NIKE link
3. Betty mentioned that the web site mapmyrun.com (from Google) might be a good link to add to the site – especially for the Nez Perce participants since they are so into exercise.
4. Cherrel mentioned that the American Diabetes Association website has a pedometer log
5. Nicole suggested looking at Leslie Sansone's website promoting walking.
6. Pam explained how NMPH has established 3 clinical teams each paired with one nurse: physician's assistant, physician, and nurse practitioner
7. Nicole asked what the initial goal for recruitment was
   a. Initially it was 50 but it was lowered to 40.

Mandan, Hidatsa and Arikara Nation (MHA Nation) – Pam Angelus
Recruitment efforts:

There are approximately 600 patients with diabetes seen at the health clinics on the reservation of the MHA Nation. The Parshall and the White Shields clinics were selected to participate in this study. Enrollment began in September 2005 and ten patients were enrolled between September and November 2005. The project status was changed to inactive in December 2005.

Of the ten patients enrolled, five had A1C numbers that were below the protocol inclusion level and needed to be removed from the project; two withdrew on their own and the remaining three were not compliant with sending in their data.

Project Team:
Deborah Hall-Thompson, the tribal health administrator is the PI for the project. Bruce Hall was the project coordinator, Shasta Mandan the nurse and Richard Mayer the CEO of MHA Nation. One nurse declined to participate and another became a participant in the study. All the physicians declined to participate.

What was Easy:
Finding and hiring the local project coordinator was done easily.

The technology – modems and cables had no problems while working with the initial ten patients.

What was Difficult:
Many of the difficulties were personnel related. The project coordinator had limited research and clinical experience. He also had limited access to patient records so was not able to easily identify patients to be recruited into the study. In general, the roles and responsibilities of the team members were not clear.

There were also many problems with missing documentation to support invoices submitted by the tribe. It took many months to get invoices paid due to missing documentation.

Lastly, the severe winters limited the amount people could get around.

Adjustments to the Site:
MHA Nation was involved in the initial design of the Native American version of the MyCareTeam site including the selection of graphics and colors to be used.

Technical and Equipment Problems:
In December 2005, IHS switched the glucose meters that were being used by the members of the MHA Nation which resulted in a change in the modem being used to transfer the glucose readings to the database. This prompted us to put the project on hold until all issues could be resolved.

Incentives:
T-shirts and coffee mugs were used as incentives to participants in the project.

In Summary:
When the project status was changed to inactive, the study coordinator was laid off and no more funds were spent on the project. ISIS continues to try and engage the tribe to restart the study.

Questions and comments posed to Pam:
1. Marjorie Mau asked if there were other competing diabetes programs in this area.

a. Pam responded that there was a clinic run by the Indian Health Service not a tribal clinic that has a diabetes program. However, it is very confusing determining who IHS employees are and who tribal employees are. There is not always cooperation between tribal and IHS employees.
2. It was then asked if the tribal clinics were busy.
   a. Yes, the White Shield clinic was pretty busy, that was why one of the nurses did not participate because she was too busy
3. Cherrel asked if the progress was made more difficult because there was no one person that said I'm going to push forward this, like a doctor.
   a. Yes, it wouldn't need to be a physician but I think it was part of the problem since there was no one willing to push the study forward. Rich Mayer (CEO of MHA Nation) would get involved periodically but it was hard to keep him involved.
   b. Pam suggested that it may just take going out to the reservation and being a presence to keep them engaged.
   c. Betty Levine suggested that since we started working with them even before the Congressional funds came through; they may have lost interest and momentum because of how long it took to get started.

Tlingit & Haida Tribes, South East Area Regional health Consortium (SEARCH) – Pam Angelus

Recruitment efforts:
The SEARHC Clinic provides medical services to Tlingit and Haida tribal members on behalf of the Tlingit and Haida tribes. There are approximately 3,500 Alaskan Natives and American Indians living in Juneau Alaska. Six-percent of AN/AI have diabetes compared to 4.5% of the general population. SEARHC provides outpatient services for about 194 individuals with diabetes.

To recruit for the project, SEAHRC personnel compiled a list of potential participants from the clinic registry. They held a lunch where they demonstrated the web site and the modem to encourage participation. They also demonstrated the web site to the providers showcasing one of their patients to encourage them to refer patients. The providers "Were amazed at the web site".

Enrollment started March 2006 and at the time of the meeting they had 9 participants enrolled but only six were actively engaged.

Project Team:
The research team consists of 2 physicians – Dr. Sheufelt who is the PI and Mary Owens, two study nurses and a physical therapist. One of the nurses, Colleen McNulty is also the project coordinator. Colleen McNulty consults with multiple providers to manage the study patients. She works with multiple physicians to coordinate medication changes and ordering of labs.

What was Easy:
The connection of the glucose meters to the modems worked very well and was easy for patients to work with.

Two computers were acquired to setup as patient kiosks in two locations. The acquisition of those computers went smoothly – however they were never setup.

What was Difficult:
Fewer patients qualified for the project than originally thought. It was difficult to identify patients with an A1C greater than 7.

Also, there were many celebrations which made it difficult for them to hold lunches and invite potential participants.

Adjustments to the Site:
Some medications were added to the web site.

Technical and Equipment Problems:
There were many problems with patients not having the correct date and time set on their glucose meter. This would result in data being sent to the database with incorrect dates and times. When the data was processed it was presented incorrectly because the timestamp for the reading was wrong. The patients were educated to check the date and time setup in their meter before taking a reading.

There was one patient that had some trouble due to the Internet Explorer Security settings on her PC. Technical support was able to work with her to solve the problem.

Incentives:
None.

In Summary:
None given.

Questions and comments posed to Pam:
None.

Papa Ola Lokahi – Pam Angelus
Recruitment efforts:
Native Hawaiians make up 20% of the total population of Hawaii, approximately 225,000 people. Two health clinics – Na Pu'uwai and Ke Ola Mamo - serve the Native Hawaiians participating in the study. Na Pu'uwai is on the island of Molokai and Ke Ola Mamo is located in Honolulu. Papa Ola Lokahi is the Native Hawaiian health administration that is overseeing the project at both clinics in Hawaii. Combined the clinics serve 250 people with diabetes.

Each clinic compiled a list of potential participants from their clinic registry and then recruited in the clinic and by phone. Enrollment is to begin in July 2006. Na Pu'uwai has already identified 9 patients to enroll and Ke Ola Mamo has identified 7.

Project Team:
Donna-Marie Palakiko, RN, MSN is the Principal Investigator/Study Coordinator at Ke Ola Mamo, and Donna Carvalho, RN, CDE is the Co-Investigator/Study Coordinator at Na Pu'uwai. There is one physician identified at each site and the project director is at Papa Ola Lokahi. Community Health Workers will help at both clinics recruit, educate, and monitor participants.

At Ke Ola Mamo, the nurse and community workers will consult with multiple providers to manage the study participants. At Na Pu'uwai the nurse and community workers will consult with one provider to manage the study participants.

What was Easy:
For us the easy parts have been traveling to Hawaii, receiving chocolate and the "hugs", and making the requested changes to the MyCareTeam web site.

W81XWH-04-2-0002

<u>What was Difficult:</u>
The most difficult part so far has been working with the local Hawaiian IRB. The process took much longer than expected.

<u>Adjustments to the Site:</u>
Changes were made to the website to incorporate the Hawaiian language, add images of Kukui trees around the clinic building (the Kukui Tree is the state tree and has some medicinal purposes), Lauhala mat on floor of virtual clinic (which is used in traditional homes and for ceremonial purposes), and links to articles on diabetes by Hawaiian authors and researchers

<u>Technical and Equipment Problems:</u>
The only technical issue so far was that Hawaii does not use daylight savings time so the vendor of the modem needed to modify their software to take that into account. Otherwise, the modem would reset the date/time stamp in the glucose meter each time the patient uploaded their glucose readings.

<u>Incentives:</u>
Gift certificates will be given to participants.

<u>Questions and comments posed to Pam:</u>
1. Robert Read asked about the enrollment numbers.
   a. Total enrollment will be 30 participants – 15 at each clinic.
2. Nicole asked if each site could have articles by local researchers.
   a. Yes, as long as they provide links to the articles or information to point to.
3. It was suggested that Diabetes Forecast has personal stories that could be added for the cultures that are focused on story tellers
4. Donna Johnson asked how it was decided to use community health nurses.
   a. Pam explained that it was the sites decision.
5. Donna Johnson also asked if any additional staff was hired.
   a. Pam replied not yet but they had not started enrolling yet.

Evaluation of Project
Inyoung Choi described how she was preparing to carry out the evaluation of the Sacred Breath Project. She described that the evaluation model consists of measuring the alignment of the clinical deployment of MyCareTeam in the different sites. She will relate the measures to the different phases of the evaluation and will use both quantitative and qualitative methods.

Inyoung will evaluate the project by examining 4 perspectives over three phases. The phases include the planning, implementation and monitoring phases. Within each of these phases, she will determine operational, technical, security, and outcome measures.

To evaluate the <u>planning phase,</u> three categories of operations will be examined: project team, diabetes management process, and IRB process. The project team will be defined and the roles of the team members identified. The diabetes management process at each site will be documented detailing how often patients visit the clinic and receive their HbA1C test. Lastly, the IRB process will be thoroughly documented what was required to receive IRB approval, how long it took to get it and what were the issues that arose across the different site.

The technical issues to be considered during the <u>planning phase</u> include hardware and software installations, network and Internet accessibility, medical device connectivity, modifications to

existing application required by the sites, and the setup and implementation of the technology into the existing diabetes programs.

The planning phase will evaluate the security of the current infrastructure, determine security requirements – both hardware and software, identify threats and security roles, and ensure the security policy is enforced.

The implementation phase focuses on operational and technical requirements. Training, workflow and patient recruitment are the key items to consider when evaluating the operational aspects of the implementation phase. Educational materials for the training program and executing the training will be performed during this phase. Current workflow for the diabetes management groups will be determined and the changes to the software that were identified are another part of the operational requirements. Lastly, patient recruitment and enrollment will be analyzed to determine its success in the implementation phase.

The technical requirements for the implementation phase include the setting up of hardware and software at each site, the configuring of the modem devices, and preparing the Internet connectivity for each site.

The monitoring phase combines operational requirements, technical requirements, security issues, and outcome evaluations. During this phase, the operational requirements and success will be measured by looking at adherence issues – frequency with which participants check their blood sugar, frequency with which they transfer those readings to the site, frequency with which they review the readings, frequency that providers review the readings, etc.

The technical success will be evaluated by looking at the technical support issues that have arisen during the monitoring phase. The number of support calls received, the number of bugs fixed, and the time spent to resolve these issues will be evaluated. Monitoring the compliance of the security policies is critical during the monitoring phase to determine if the confidential information has remained secure.

During the monitoring phase we will be able to evaluate the project looking at both clinical and other outcomes. The clinical outcomes to be evaluated include change in HbA1C values, cholesterol measures, number of hypo- and hyper- glycemic events, etc. Some of the other outcome measures include patient satisfaction, frequency of use, and ease of use.

Lessons Learned
Two things that increase the probability of success at each clinic appear to be a strong local clinical coordinator and a well defined existing diabetes management program. The role of the local project coordinator at each clinic is critical to the success of the project since they deal directly with the patients and the providers and are the ones that actually encourage the use of the system. If a site has a well defined process for managing their patients with diabetes, incorporating the technology into that program is simpler than trying to implement the technology into a clinic without a well defined diabetes management program.

The sites that have a local technical support person actually do better with implementing the technology than those sites without local support. The sites with the support can trouble shoot issues more quickly and provide more detailed descriptions of problems to the ISIS Center.

W81XWH-04-2-0002

During the monitoring phase, it is critical to continuously encourage patients and providers to use the system and communicate via the application as opposed to waiting for patients to visit the clinic or making a phone call.

Questions and Comments for Inyoung
1. Cherrel Christian asked if a survey was planned for providers.
   a. It was discussed but at any given site there are only 1 to 3 providers so we didn't end up doing a survey. We have discussed talking with them one and one to get their feedback. Much of their feedback is given through weekly or bi-weekly conference calls already.
2. Bette Keltner provided some insight into our evaluation plan as follows: Feedback would be possible, but because the number of providers is so small the feedback won't be anonymous so the information received may not be very useful. Evaluation is focused on what works for what people under what conditions? Well informed site coordinators can drill down and make sure we receive feedback from the providers. The site coordinators can also help to determine if this program is a vehicle that is attractive to older people? To Women? This type of information could be useful for further defining the outreach of Sacred Breath. It is especially important to understand the conditions where our sites are located, and the kinds of human interaction that may not be face to face but where the person serves as an intermediary that engages groups of people. In the evaluation plan, I like how you outline it because it's so clear, the change of events. It allows a comprehensive and continuous result.
3. A discussion followed about whether we had enough data to state anything statistically?
   a. We may be able aggregate the number of patients in all our native communities to get a large enough sample size. However, we don't have a control group but we have their initial A1C level from before they came into the program. We can look at the frequency with which people use this program. Thus we can answer the question, "Do people use it"? "Is it acceptable"?
   b. Mike Ackerman said yes we could look at those questions, but that's not going to get us more funding.
   c. Robert Read said but that will help looking at the satisfaction data.
   d. We can mine down into the messages sent between patients and their providers to gain insight into their satisfaction. It's another piece of information we can get out of the data. We can see how the patients and providers use the online technology, the types of questions they ask. Hopefully, the data will tell us definitely whether there have been improvements in clinical outcomes. One thing in our favor is the two studies that were previously completed showing positive clinical outcomes by those individuals that used the technology. These studies were both published and showed marked improvement in HbA1C for patients using the technology compared to those that didn't use it.
4. Nicole Johnson asked if some question on the survey or a component of it dealt with psycho-social issues. Do the patients using the system have more confidence? Are they less depressed? She described that people may see a number and if it's a bad number they don't want to test again since they don't want to see another bad number. She wanted to know if there were some ways to see if there was a shift in that psychology.
   a. Cherrel followed up with, "Are people having a more developed conversation with their provider at that 3 month visit, b/c they have more info?"
   b. We did not ask psycho-social questions like that on the survey so we have no real way of knowing the answer.
   c. Nicole followed up with we might be able to make more of a long-term impact on peoples state of mind or mood.

d. Cherrel said that at NNMC when a physician adjusts a mother's insulin, they say that you need more insulin because this is what is expected during pregnancy which keeps the mother from thinking she did something wrong

e. Jim Mingle responded that it's not what you say but how you say it.

f. Seong K. Mun stated that we are not experts in this field and this is where we rely on consultants who are experts.

g. Marjorie Mau summarized that what we are trying to measure the use of technology in a set program and to evaluate its effect in a different environments we could use process measures. She described that we could also use value measures which have built in validity but she didn't get the sense that that's what we want to measure. She described it as us measuring the impact of the technology and she pointed out that the project coordinators have intimate knowledge of implementing these technologies in difficult environments.

h. Seong K. Mun described how we had to start from scratch and build infrastructure especially as it relates to recruiting patients. Many of the sites did not have a process in place for doing that. He described how difficult it was to implement this type of program in a location without the infrastructure for diabetes management – with or without the technology.

i. Betty Levine described that other projects have been unsuccessful because they have not been able to recruit participants.

j. Again Marjorie Mau stated that recruiting was easier when they had an existing clinic like at NNMC. This provided existing means to tap into an existing clinic population and it becomes fairly clear as to how that's done. In the Pacific, the question patients ask is "What is the added value to my care?" For the providers it is "What is the added value to my patient?" For some it was that they didn't have to come into DC and battle the traffic. She is not sure what the incentives are for other groups. There is added value above and beyond their original care if they embraced the technology.

k. Cherrel felt the added value was the patient feeling like the provider spent additional time on their care – gave them that pat on the back.

l. Robert Read asked why the program was different than an office visit where the patient could get the same attention.

m. Bette Keltner questioned whether we could test end measures to get a sense of proportionality.

n. Pam Angelus mentioned that another added value is giving time back to the provider. Especially while treating pregnant women with diabetes, providers /nurses spend time calling patients to record their blood sugar readings.

o. Bette Keltner replied that that needed to be tested.

p. Pam Angelus stated that since we have not gotten the provider support that we had hoped for, it will be difficult to test that. However, one of our goals was to give time back to the providers by their using this tool.

q. Jim Mingle mentioned that the bigger issue on the provider side was reimbursement. Providers and especially physicians want to be paid for their time. Doctors see this as another thing they have to do that they won't get paid for. Kaiser is starting to pay physicians $10 per message if they email their patients but it has to be worked out through state and federal governments.

r. Marjorie Mau stated that in Hawaii 90 of Hawaiians are covered by insurance but they have yet to see the benefits of the foot and eye exams being provided.

s. Bette Keltner noted that the system is driven for the benefit of providers and there has to be that incentive, but how does that become more efficient in an industry that is spiraling out of control in terms of costs, there is too much at stake.

W81XWH-04-2-0002

t. Betty Levine pointed out that the nurse's time is freed up but that does not help with reimbursement issues since the nurses are salaried employees. A good time motion study is needed.

u. It was pointed out that billing becomes very important in physician offices and often nurses are reduced. Therefore their workload increases and until technology is embraced it is difficult to see how this will be changed.

v. The concept of pay for performance for physicians came up and how that might "encourage" a physician to use a tool like this.

Next Meeting
1. Plan the next meeting in about 6 – 12 months
2. Invite the sites again to share their experiences
3. Provide opportunities for discussions
4. Hold the meeting at one of the Native sites – possibly Idaho

Commercialization
Betty Levine and Jim Mingle described the commercialization effort of MyCareTeam. The history behind the MyCareTeam software is:

a. It came to life in 1999
b. First pilot studied completed December 2000
c. Large clinical trial October 2001 to April 2004
d. Filed patent application in October 2001 – patent is still pending
e. Filed for copyright January 2001 and received it February 2002
f. In the process of registering the MyCareTeam logo
g. Entered discussions w/ Jim Mingle in November 2004 while talking with other companies as well
h. Jim came through with a business plan
i. September 2005 GU entered licensing agreement with MyCareTeam Inc

Jim Mingle then discussed the different offerings that the company has for the MyCareTeam application:

a. Personal version – allows individuals to manage their own disease while inviting friends and relatives to help as support "buddies"
b. Professional version – follows the original intent of the software designed at GU where the health care provider provides the support

Georgetown University started with the professional version and the company still thinks there is a market for this. It aggregates people and really makes sense for identifying who needs attention. However, the company decided to lead with the personal version. The personal version allows one to help a family member, friend or love one manage their diabetes. A mom or dad can manage their kid's diabetes when they first go off to college; and adult child can help an elderly parent living in Florida; sometimes, the family member of a person with diabetes feels more guilt about not being able to help.

The company modified the site to make it easy for an individual to register on the site and to invite others to join their support team; to print logs and reports; to read data from multiple meters seamlessly.

MyCareTeam, Inc is currently establishing partnerships with different organizations and key players in distinct industries. They can modify the software such that it looks like another com-

pany or organizations' website (the software is really MyCareTeam) in order to "skin" the site if they enter into a relationship with a company or organization.

The goal of MyCareTeam, Inc is to get the technology into the hands of as many people as possible. Cost should not be a limiting factor stopping anyone from using the technology.
The users can easily print out reports that they can bring to their doctor while using any vendor's glucose meter.

The commercial version is now in a beta test and they have shown they can read from more than 19 different glucose meters.

Questions and comments for Betty and Jim
1. Betty explained that each of the Sacred Breath sites were curious what would happen at the end of the project period if they found the technology useful. We explained that the commercialization effort allowed us to offer the technology to them at minimal cost after the end of the study period.
2. Nicole asked if we could have a larger group of participants to improve our enrollment numbers. We continue to submit grants, some of which include working with My-CareTeam, Inc, to expand the technology, the disease states and the number of enrollees. Seong K. Mun expressed that getting research funding to explore other questions that were raised today is difficult.
3. Jim Mingle asked if we thought about what would happen if we offered incentives to people to participate. Dr. Mun responded that you can offer incentives indefinitely.
4. Reimbursement was raised again and this time Seong K. Mun said he felt it would get handled eventually.
5. Discussion about how much you want someone supporting or watching over you came up. Nicole expressed that sometimes it is just too much and you don't want it. She's not sure the right answer.

Sacred Breath
2nd Advisory Board Meeting Agenda

Location:
ISIS Center
Georgetown University
Room 603
2115 Wisconsin Ave, NW
Washington, DC 20057
202-687-5990

Time	Agenda Item	Presenter
10:00	Introductions & Welcoming Remarks	Seong K. Mun
10:30	Opening Statement & Agenda Review	Marjorie Mau
10:45	Sacred Breath Reports and Discussion	
	• Status Report	Betty Levine
	• Site Reports	
	○ National Naval Medical Center	Cherrel Christian
	○ Poarch Band of Creek Indians	Donna Johnson
	○ Nez Perce	Jaci McCormack
	○ Tlingit and Haida Tribes (SEARHC)	Pam Angelus
	○ Papa Ola Lokahi	Pam Angelus
	○ Mandan, Hidatsa, & Arikara Nation	Pam Angelus
	• Discussion of Site Reports	Marjorie Mau
1:00	Lunch & Continued Discussion of Morning Presentations	
2:00	Evaluation of Project	Inyoung Choi
2:20	Commercialization Effort	Betty Levine
2:45	Open Discussion	Marjorie Mau
	• Sustainability	
	• Adding Other Chronic Diseases	
	• Expanding to Other Communities	
	• Improving Patient Enrollment & Involvement	
	• Improving Provider Participation	
3:45	Closing Remarks	Marjorie Mau Seong K. Mun